IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	MICHELSON *et al.*	Art Unit:	To be assigned
Appln. No.:	To be assigned	Examiner:	To be assigned
Filed:	Herewith	Atty. Docket:	16602.003
For:	Systems and Methods for Selecting and Recruiting Investigators and Subjects for Clinical Studies		

Preliminary Amendment

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Prior to examination on the merits, Applicants hereby request entry of the following amendments in the above-captioned application:

In the Specification:

On page 1, lines 1-2, please replace the title of the application with the following:

SYSTEMS AND METHODS FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES

Please delete the paragraph on page 13, beginning on line 16 and ending on 18, and replace it with:

Figs. 4A, 4B, 4C and 4D depict an exemplary web page through which a person submits one or more disease conditions of interest to a database for identifying eligible subjects for a clinical study, in accordance with the present invention.

Please delete the paragraph on page 13, beginning on line 19 and ending on line 20, and replace it with:

Figs. 5A through 5J depict an exemplary web page which conveys to a registered user information about clinical studies, in accordance with the present invention.

Please delete the paragraph on page 13, beginning on line 21 and ending on line 23, and replace it with:

Figs. 6A through 6R depict a series of exemplary web pages through which a person can search clinical studies and opt to receive information about clinical studies in one or more selected therapeutic areas, in accordance with the present invention.

Please delete the paragraph on page 14, beginning on line 1 and ending on line 3, and replace it with:

Figs. 7A through 7E depict an exemplary web page that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with the present invention.

Please delete the paragraph page 14, beginning on line 4 and ending on line 5, and replace it with:

Figs. 7F to 7J depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention.

Please delete the paragraph on page 14, beginning on line 6 and ending on line 7, and replace it with:

Figs. 8A and 8B depict a flow diagram showing the steps performed by a sponsor using the professional site to recruit subjects, investigators, arid take steps necessary to start a clinical study.

Please delete the paragraph on page 14, beginning on line 8 and ending on line 9, and replace it with:

Figs. 9A and 9B depict an exemplary web page used by a sponsor to enter study parameters into the system.

Please delete the paragraph on page 14, beginning on line 10 and ending on line 11, and replace it with:

Figs. 10A and 10B depict an exemplary web page used by a sponsor to enter criteria necessary to initiate an investigator search.

Please delete the paragraph on page 14, beginning on lines 18 and ending on line 19, and replace it with:

Figs. 15A through 15H depict an exemplary study-specific subject questionnaire used for prescreening a subject for a clinical study.

Please delete the paragraph on page 15, beginning on line 13 and ending on line 14, and replace it with:

Figs. 22A through 22K depict an exemplary data structure for implementing an investigator database, in accordance with the present invention.

Please delete the paragraph on page 15, beginning on line 15 and ending on line 16, and replace it with:

Figs. 22L-P depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection, in accordance with the present invention.

Please delete the paragraph on page 15, beginning on line 18 and ending on line 19, and replace it with:

Figs. 24A through 24E depict an exemplary data structure for implementing a subject database, in accordance with the present invention.

Please delete the paragraph on page 15, beginning on line 22 and ending on line 23, and replace it with:

Figs. 26A and 26B depict an exemplary data structure used for implementing the sponsor access limitations shown in Fig. 23.

Please delete the paragraph beginning on page 22, line 13 and ending on page 23, line 10, and replace it with:

Referring still to Figure 1, system 100 also includes an integrated investigator database. In one embodiment, the investigator database includes information from three general sources as described below, although in other embodiments it may include information from a lesser or greater number of sources or different sources. First, the investigator database includes data about the clinical study investigators who wish to inform clinical study sponsors of their clinical study experience and/or training, submitted by the investigators themselves. This self-reported data is typically entered into the investigator database either when a given investigator logs onto the professional site and registers with the system as described further with reference to Figs. 7A through 7E or by submitting such information to the professional site by mail, fax, phone or other non-computerized means. The self-reported data includes various types of information including, for example, the educational background of the investigator, the clinical study experience of the investigator, the past performance of the investigator in other clinical studies (e.g., how many subjects the investigator committed to recruit for a given study and in what period of time, how many subjects the investigator actually recruited for the study and in what period of time, and how many of such subjects actually completed the study), equipment available to the investigator (e.g., whether or not the investigator has access to a CAT scan machine or MRI equipment which may be required for a given study), any mandated IRB

relationships of the investigator (e.g., whether or not the investigator is required through professional affiliations to submit materials to a particular IRB for approval before the materials may be used to advertise the study), any hospital or HMO affiliations of the investigator, information about the investigator's staff and facilities and the geographic location of the investigator.

Please delete the paragraph on page 26, beginning on line 12 and ending on line 21, and replace it with:

Figs. 4A through 4D depict an exemplary web page of subject sites through which a person may submit one or more disease conditions to a database for identifying eligible subjects for a clinical study, in accordance with the present invention. Therapeutic area web page 400 includes pull down menu 401 at which a person may identify a therapeutic area of interest to that person. In this example, the therapeutic area cancer has been chosen. Upon clicking on view button 402, the potential disease conditions of interest are presented to the subject or caregiver in disease condition area 403. The person may check one or more boxes in medical news/drug area 404 or clinical study opportunities area 405 to indicate if the person is interested in obtaining medical news, drug or clinical study opportunity information on any of the disease conditions specified in disease condition area 403.

Please delete the paragraph beginning on page 26, line 22 and ending on page 27, line 4, and replace it with:

Figs. 5A through 5J depict an exemplary web page of the subject site, which conveys information about clinical studies, and provides an ability to search clinical studies to a registered user, in accordance with the present invention. Frequently asked questions area 503 is provided to educate a person on clinical studies. In search area 501, the registered user may

click on any one of the therapeutic areas identified (such as cancer clinical study area 502) and be taken to a search clinical study web page 600, as depicted in Figs. 6A and 6B.

Please delete the paragraph on page 27, beginning on line 12 and ending on line 20, and replace it with:

Upon clicking on contact area 604, the user will be taken to general study interest web page 605 shown in Figs. 6C and 6D. On general study interest web page 605, the registered user may indicate in interest area 606 whether the registered user is interested for himself/herself or for someone else. In one embodiment, the registered user may select in selection area 607 up to three therapeutic areas in which the registered user is interested. In contact area 608, the registered user indicates the manner in which the registered user would like to be contacted, e.g., by e-mail, telephone or regular mail. The registered user also indicates name and contact information in contact information area 609. The registered user submits the form by clicking on submit button 610, or may cancel the process by clicking on cancel button 611.

Please delete the paragraph on page 28, beginning on line 3 and ending on line 16, and replace it with:

In an alternative embodiment, in order to become a user registered with the subject database, the user will be required to provide the information required as shown in the web page depicted in Fig. 6E: a user id; password; password reminder; and whether the user is seeking information for himself or herself or for someone else. In a second step, with reference to Figs. 6F and 6G, the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as medical conditions experienced by the user, salutation, last

name, ethnic background, telephone number, country of residence, as shown in Fig. 6F. In a third step 3, the user inputs information on a web page such as that shown in Fig. 6H, including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in Figs. 6F and 6G. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions governing the user's use of the inventive system.

Please delete the paragraph beginning on page 28, line 17 and ending on page 29, line 3, and replace it with:

Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page depicted in Fig. 6I. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the riser may be taken to a web pages such as those depicted in Figs. 6J through 6N and provide information such as the type of prescriptions or over-the-counter medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In Fig. 6O, the user can see if the user has answered completely questions about each medical condition previously listed by the user. In Fig. 6P, the user can provide feedback. In Fig. 6Q, the service provider may provide a thank you to indicate that the message was sent successfully.

Please delete the paragraph on page 29, beginning on line 4 and ending on line 12, and replace it with:

The registered user may also access, on the subject site, the registered user's own personal library. Library web page 612, shown in Fig. 6R, informs the registered user that he or she may maintain a personal library of information relating to clinical studies or new

developments related to particular therapeutic areas found throughout the subject site. The user may also create and save personal notes relating to the same. Information may be placed in the library by the registered user or, in some embodiments, specific information on topics which may be of interest to the registered user may be placed in the registered user's library automatically based on, for example, the registered user's past selections of information to place in the library, therapeutic areas of interest, disease conditions of interest, geographic location, and/or gender.

Please delete the paragraph beginning on page 29 line 14 and ending on page 30, line 6, and replace it with:

An investigator who is interested in conducting clinical studies may express his or her interest by registering on the professional site of Fig. 1B. Figs. 7A, 7B, 7C, 7D, and 7E depict investigator questionnaire web page 700 that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with an embodiment of the present invention. In name area 701, the investigator is required to input his or her name. In degree area 702, the investigator's degree(s) are required. The PRF organization or institutional name, address, city state, country, zip code and telephone number are required (and fax and electronic snail address optionally requested) in contact area 703. Specialty area 704 requires that the investigator provide his or her primary specialty area. Board area 705 requires that the investigator indicate whether he or she is board certified and/or board eligible; optionally, the investigator's year of primary specialty board certification, and board information regarding any of the investigator's subspecialties may be provided. In study experience area 706, the investigator is required to indicate the number of years the investigator has participated in clinical studies as well as all phases of clinical research in which the investigator has

participated. The investigator must include the number of investigators that conduct research at the PRF indicated in investigator area 707.

Please delete the paragraph on page 31, beginning on line 2 and ending on line 9, and replace it with:

Figs. 7F to 7G depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention. Fig. 7F is directed to persons that register with the subject or investigator site based on a visit to the subject site; Fig. 7G is directed to persons that register with the subject or investigator site based on a contact with a pharmaceutical call center; Figs. 7H and 7J are directed to persons that register with the subject or investigator site based on a contact with an off-line call center and Fig. 7J is directed to persons that register with the subject or investigator site based on a visit to a third party on-line recruitment site.

Please delete the paragraph on page 31, beginning on line 11 and ending on line 15, and replace it with:

Referring now to Figures 8A and 8B, there is shown a flow diagram of a process that may be used by a sponsor to accomplish the steps necessary to start a clinical study. The process may begin at two different points. Specifically, if the sponsor wishes to begin by making a feasibility assessment with respect to the study, the process starts at step 804. Alternatively, if the sponsor does not wish to make a feasibility assessment, the process starts at step 811.

Please delete the paragraph beginning on Page 33, line 15 and ending on page 34, line 8, and replace it with:

The sponsor reaches step 811 either as an entry point into the process, or after the sponsor has determined in step 810 that the study is feasible. In step 811, tile sponsor determines

whether the sponsor desires to use the investigator database to perform investigator recruitment for the study. If the sponsor wishes to use the investigator database for investigator recruitment, then in step 815, the sponsor begins by entering study parameter information into the system. A screen shot of a web page that may be used for entering this information is shown in Figures 9A and 9B. In this step, the sponsor enters various parameters about the study into the system. Next, in step 816, the sponsor enters investigator search criteria for the study into the system. Such search criteria could include, for example, one or more specialties that would be desirable for an investigator for the study, information about the prescribing behavior of the investigator, the number of studies that the investigator has conducted, the therapeutic area and disease indication associated with clinical studies previously conducted by the investigator, the distance around the investigator site in which subjects participating in the study should be sought, and the geographic area in which the investigator should be located. Figures 10A and 10B depict a screen shot of an exemplary web page that may be used by a sponsor to input the investigator search criteria into the system. In step 818, the sponsor is given the ability to weigh one or more of the investigator criteria prior to initiating the investigator search.

Please delete the paragraph beginning on Page 34, line 18 and ending on page 35, line 8, and replace it with:

An exemplary web page that shows the results of an investigator search in accordance with the present invention is shown in Figs. 11A and 11B. As shown in that figure, for each investigator identified in the search, the sponsor is shown the name of the investigator, the investigator's specialty, the city/state in which the investigator is located, the number of studies that the investigator has performed, subject demographic information obtained from the TIA database (i.e. the number of persons listed in the TIA database that are within a predetermined

distance of the investigator site and who could potentially qualify as subjects for the clinical study), subject demographic information obtained from the subject database (i.e. the number of subjects listed in the subject database that are within a predetermined distance of the investigator site and who could potentially qualify to participate in the clinical study), the drug prescribing behavior of the investigator (e.g., the drug class prescribing decile associated with the investigator). It will be understood by those skilled in the art that other criteria relevant to the investigator could also be shown on this search results screen including for example, the behavior of the investigator with respect to ordering of laboratory tests/procedures.

Please delete the paragraph beginning on Page 36, line 22 and ending on page 37, line 19, and replace it with:

After a potential subject has been identifies (step 817 or 819), the process of pre-screening for participation in the study begins (step 824). In this step, subjects identifies using on-line and/or offline recruitment are notified, and asked whether or not they have an interest in participating in the clinical study. In the case of candidates that were identified on-line using the subject database, the subjects are preferably contacted by the means that they identified during their registration, on the subject site (e.g., by electronic mail) in order to preliminarily determine whether they have an interest in participating in the clinical study. A screen shot of an exemplary e-mail used for providing such a notification to a potential subject is shown in Fig. 14. The notification could alternatively be provided using telephone, mail, fax or any off line communication means. If a potential subject responds to a notification by indicating interest in participating in a clinical study, the subject is provided with a formal questionnaire that asks for information specifically relevant to the clinical study. An exemplary study-specific subject questionnaire is shown in reference to Figs. 15A-15H. In the preferred embodiment, if in

response to the e-mail notification shown in Fig. 14, the subject indicates interest in participating in the clinical study, a study-specific subject questionnaire such as shown in Figs. 15A-15H is provided to the subject on a secure web page found on the subject site. The subject then uses this secure web page to answer all of the questions in the subject questionnaire, and to submit such answers for consideration. As mentioned above, irrespective of whether the subject is ultimately selected for participation in the clinical study, these questionnaire answers are stored in the subject database with the consent of the patient, thereby enriching the subject information stored in that database.

Please delete the paragraph on page 39, beginning on line 2 and ending on 7, and replace it with:

Fig. 16 is a process flow diagram of a method for identifying eligible investigators for a clinical study in accordance with one embodiment of the present invention. Specifically, at step 1610, information is stored in database 2200 of the inventive system (in particular, the data is stored in table 2252, field 2252a of Fig. 22E) relating to the geographic location of each of a plurality of investigators. At step 1620, an incidence or a prevalence of each of a plurality of disease conditions in a plurality of different geographic locations is stored in the database.

Please delete the paragraph on page 46, beginning on line 13 and ending on line 18, and replace it with:

At step 2141, information is stored in the database that associates the types of equipment that an investigator has with one or more disease condition. At step 2142, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease

condition and related equipment that an investigator has. At step 2143 the inventive system identifies an investigator based upon the query results and the investigator's equipment.

Please delete the paragraph beginning on Page 46, line 19 and ending on page 47, line 2, and replace it with:

Fig. 21L is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2143', information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator practice setting, which is where the actual clinical study is conducted, and where a subject would most likely go to participate. 'this information is provided by the investigator.

Please delete the paragraph beginning on Page 59, line 15 and ending on page 60 line 2, and replace it with:

Fig. 22A through 22K is an exemplary data structure for implementing an investigator database 2200. For example, table 2210 includes investigator data related to basics such as name, age, address, phone, etc. Table 2220 contains data about a specific study performed by the investigator, Table 2230 relates to the investigator's specialties, and Table 2240 relates to the investigator's subject population. Shown in Figs. 22C and 22E, table 2250 contains data about the investigator's staff. Table 2260 of Fig. 22F contains data regarding the investigator's hospital affiliations. It will be understood by those skilled in the art that the investigator database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Figs. 22A thorough 22K represents one example of such a data structure.

Please delete the paragraph on page 60, beginning on line 4 and ending on line 20, and replace it with:

Figs. 22L-P depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection. The example shown relates specifically to use of the invention to perform a study related to the disease of angina. Initially, the TlA database is queried using angina as the query criterion to identify geographic locations where the incidence of angina is more prevalent. These areas are identified on a national basis in Fig. 22L, and specifically for the Dallas-Fort Worth area in Fig. 22M. It bears noting that, within the Dallas-Fort Worth area, the TlA database IMS further identified an incidence value for each sub-region of the Dallas-Fort Worth area. Sites of various investigators in Dallas-Fort Worth that are potentially eligible to perform the study are also shown on Fig. 22M. These investigator sites were found by querying the investigator database as described above. Fig. 22N shows that there are three eligible investigator sites in the Dallas-Fort Worth Area. These three investigator sites are shown as circled stars in Fig. 22N. Of the three eligible investigator sites, one of the investigator sites is located in a sub-region having a higher incidence of angina than is found in the sub-regions of the other two eligible investigators. As shown in Fig. 22O, the investigator located in the sub-region having the highest incidence of angina is next selected to perform the study. Following selection of this investigator for the study, subjects closest to the site of the selected investigator are identified for screening, as shown in Fig. 22P.

Please delete the paragraph on page 61, beginning on line 12 and ending on line 15, and replace it with:

Fig. 23 is a screen shot showing sponsor access limitations to study data. Aggregated data 2302 can be viewed by all sponsors, whereas data 2304 can only be viewed by the sponsor that

supplied that data 2304 to the database. Figs. 26A and 26B depict an exemplary data structure used for implementing the sponsor access limitations discussed above.

In the Claims:

Please delete claims 16-120 and add new claims 121-128

Claim 121 (New) A method for recruiting a person to participate as a subject in a clinical study, comprising:
(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database;
(b) registering automatically the person or caregiver with the database upon receipt of the registration information;
(c) determining automatically in accordance with the registration information whether to provide the person or caregiver with notice of a given clinical study associated with a therapeutic area, disease, or condition of interest to the person; and
(d) providing the person or caregiver with notice of the given clinical study if a determination is made to provide such notice.

Claim 122 (New) The method as in claim 121, wherein said information comprises a geographic location of the person, a therapeutic area, disease, or condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies.

Claim 123 (New) A method for recruiting a person to participate as a subject in a clinical study, comprising:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to transfer information about the person over the Internet to a database;
(b) determining automatically in accordance with said information whether to provide the person or caregiver with notice of a given clinical study associated with a therapeutic area, disease, or condition of interest to the person; and
(c) providing the person or caregiver with notice of the given clinical study if a determination is made to provide such notice.

Claim 124 (New) The method as in claim 123, wherein said information comprises a geographic location of the person, a therapeutic area, disease, or condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies.

Claim 125 (New) The method as in claim 123 further comprising registering said information in a database.

Claim 126 (New) A method for recruiting a person to participate as a subject in a clinical study, comprising the step of presenting one or more web pages that allow the person or a caregiver associated with the person to transfer information about the person over the Internet to a database.

Claim 127 (New) The method as in claim 126, wherein said information comprises geographic location, zip code of residence, e-mail address, and contact information.

Claim 128 (New) The method as in claim 126, wherein said information comprises specific information about said person's medical condition, disease status, symptoms, duration of illness, medications taken, and prior treatment options.

Remarks

Support for the added claims can be found throughout the specification and in the claims as filed. No new matter enters by this amendment.

Applicants note that 114 sheets of formal drawings are attached to this preliminary amendment for replacement of the informal drawings that were included with the filing of parent application number PCT/US01/02936. Applicants note that the figures have been reformated in order to comply with 37 C.F.R.. Some numbers and letters in some figure headings have been relabelled in the process. No new matter has thereby been introduced.

Applicants note that a petition to make special also accompanies this amendment and add that if the Examiner believes for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to Arnold & Porter Deposit Account No. 50-1824.

Prompt and favorable consideration of the application is respectfully requested.

Respectfully submitted,

Joseph A. Micallef (Reg. No. 39,772)
Andrew S. Brenc (Reg. No. 45,534)

Date: _____

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Marked-Up Specification

On page 1, lines 1-2

SYSTEMS AND METHODS FOR SELECTING AND RECRUITING [INVESTIGATIONS] INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES

On page 13, lines 16-18

Figs. 4A, 4B[and 4C], 4C and 4D depict an exemplary web page through which a person submits one or more disease conditions of interest to a database for identifying eligible subjects for a clinical study, in accordance with the present invention.

On page 13, lines 19-20

Figs. 5A through [5F] 5J depict an exemplary web page which conveys to a registered user information about clinical studies, in accordance with the present invention.

On page 13, lines 21-23

Figs. 6A through [6N] 6R depict a series of exemplary web pages through which a person can search clinical studies and opt to receive information about clinical studies in one or more selected therapeutic areas, in accordance with the present invention.

On page 14, lines 1-3

Figs. 7A[, 7B 7C] through 7E depict an exemplary web page that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with the present invention.

On page 14, lines 4-5

Figs. [7D to 7G] 7F to 7J depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention.

On page 14, lines 6-7

Figs. 8A and 8B depict [is] a flow diagram showing the steps performed by a sponsor using the professional site to recruit subjects, investigators, arid take steps necessary to start a clinical study.

On page 14, lines 8-9

Figs. 9A and 9B depict [is] an exemplary web page used by a sponsor to enter study parameters into the system.

On page 14, lines 10-11

Figs. 10A and 10B depict [is] an exemplary web page used by a sponsor to enter criteria necessary to initiate an investigator search.

On page 14, lines 18-19

Figs. 15A through [15F] 15H depict [is] an exemplary study-specific subject questionnaire used for prescreening a subject for a clinical study.

On page 15, lines 13-14

Figs. 22A through [22F] 22K depict an exemplary data structure for implementing an investigator database, in accordance with the present invention.

On page 15, lines 15-16

Figs. 22[G-K]L-P depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection, in accordance with the present invention.

On page 15, lines 18-19

Figs. 24A through [24D] 24E depict an exemplary data structure for implementing a subject database, in accordance with the present invention.

On page 15, lines 22-23

Figs. 26A and 26B depict[s] an exemplary data structure used for implementing the sponsor access limitations shown in Fig. 23.

On page 22, line 13 through page 23, line 10

Referring still to Figure 1, system 100 also includes an integrated investigator database. In one embodiment, the investigator database includes information from three general sources as described below, although in other embodiments it may include information from a lesser or greater number[s] of sources or different sources. First, the investigator database includes data about the clinical study investigators who wish to inform clinical study sponsors of their clinical study experience and/or training, submitted by the investigators themselves. This self-reported data is typically entered into the investigator database either when a given investigator logs onto the professional site[,] and registers with the system as described further with reference to Figs. 7A through [7C] 7E or by submitting such information to the professional site by mail, fax, phone or other non-computerized means. The self-reported data includes various types of information including, for example, the educational background of the investigator, the clinical study experience of the investigator, the past performance of the investigator in other clinical studies (e.g., how many subjects the investigator committed to recruit for a given study and in what period of time, how many subjects the investigator actually recruited for the study and in what period of time, and how many of such subjects actually completed the study), equipment available to the investigator (e.g., whether or not the investigator has access to a CAT scan machine or MRI equipment which may be required for a given study), any mandated IRB relationships of the investigator (e.g., whether or not the investigator is required through professional affiliations to submit materials to a particular IRB for approval before the materials may be used to advertise the study), any hospital or HMO affiliations of the investigator,

information about the investigator's staff and facilities and the geographic location of the investigator.

On page 26, lines 12-21

Figs. 4A through 4[C]D depict an exemplary web page of subject sites through which a person may submit one or more disease conditions to a database for identifying eligible subjects for a clinical study, in accordance with the present invention. Therapeutic area web page 400 includes pull down menu 401 at which a person may identify a therapeutic area of interest to that person. In this example, the therapeutic area cancer has been chosen. Upon clicking on view button 402, the potential disease conditions of interest are presented to the subject or caregiver in disease condition area 403. The person may check one or more boxes in medical news/drug area 404 or clinical study opportunities area 405 to indicate if the person is interested in obtaining medical news, drug or clinical study opportunity information on any of the disease conditions specified in disease condition area 403.

On page 26, line 22 through page 27, line 4

Figs. 5A through 5[F]J depict an exemplary web page of the subject site, which conveys information about clinical studies, and provides an ability to search clinical studies to a registered user, in accordance with the present invention. Frequently asked questions area 503 is provided to educate a person on clinical studies. In search area 501, the registered user may click on any one of the therapeutic areas identified (such as cancer clinical study area 502) and be taken to a search clinical study web page 600, as depicted in Figs. 6A and 6B.

On page 27, lines 12-20,

Upon clicking on contact area 604, the user will be taken to general study interest web page 605 shown in Figs. 6C and 6D. On general study interest web page 605, the registered user

may indicate in interest area 606 whether the registered user is interested for himself/herself or for someone else. In one embodiment, the registered user may select in selection area 607 up to three therapeutic areas in which the registered user is interested. In contact area 608, the registered user indicates the manner in which the registered user would like to be contacted, e.g., by e-mail, telephone or regular mail. The registered user also indicates name and contact information in contact information area 609. The registered user submits the form by clicking on submit button 610, or may cancel the process by clicking on cancel button 611.

On page 28, lines 3-16

In an alternative embodiment, in order to become a user registered with the subject database, the user will be required to provide the information required as shown in the web page depicted in Fig. 6[D]E: a user id; password; password reminder; and whether the user is seeking information for himself or herself or for someone else. In a second step, with reference to Figs. 6[E]F and 6G, the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as medical conditions experienced by the user, salutation, last name, ethnic background, telephone number, country of residence, as shown in Fig. 6F. In a third step 3, the user inputs information on a web page such as that shown in Fig. 6[F]H, including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in Figs. 6[E]F and 6G. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions governing the user's use of the inventive system.

On page 28, line 17 through page 29, line 3

Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page depicted in Fig. 6[G]I. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the riser may be taken to a web pages such as those depicted in Figs. 6[H]J through 6[J]N and provide information such as the type of prescriptions or over-the-counter medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In Fig. 6[K]O, the user can see if the user has answered completely questions about each medical condition previously listed by the user. In Fig. 6[L]P, the user can provide feedback. In Fig. 6[M]Q, the service provider may provide a thank you to indicate that the message was sent successfully.

On page 29, lines 4-12

The registered user may also access, on the subject site, the registered user's own personal library. Library web page 612, shown in Fig. 6[N]R, informs the registered user that he or she may maintain a personal library of information relating to clinical studies or new developments related to particular therapeutic areas found throughout the subject site. The user may also create and save personal notes relating to the same. Information may be placed in the library by the registered user or, in some embodiments, specific information on topics which may be of interest to the registered user may be placed in the registered user's library automatically based on, for example, the registered user's past selections of information to place in the library, therapeutic areas of interest, disease conditions of interest, geographic location, and/or gender.

On page 29 line 14 to page 30, line 6

An investigator who is interested in conducting clinical studies may express his or her interest by registering on the professional site of Fig. 1B. Figs. 7A, 7B[and 7C], 7C, 7D, and 7E depict investigator questionnaire web page 700 that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with an embodiment of the present invention. In name area 701, the investigator is required to input his or her name. In degree area 702, the investigator's degree(s) are required. The PRF organization or institutional name, address, city state, country, zip code and telephone number are required (and fax and electronic snail address optionally requested) in contact area 703. Specialty area 704 requires that the investigator provide his or her primary specialty area. Board area 705 requires that the investigator indicate whether he or she is board certified and/or board eligible; optionally, the investigator's year of primary specialty board certification, and board information regarding any of the investigator's subspecialties may be provided. In study experience area 706, the investigator is required to indicate the number of years the investigator has participated in clinical studies as well as all phases of clinical research in which the investigator has participated. The investigator must include the number of investigators that conduct research at the PRF indicated in investigator area 707.

Page 31, lines 2-9

Figs. [7D to 7G] 7F to 7G depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention. Fig. 7[D] F is directed to persons that register with the subject or investigator site based on a visit to the subject site; Fig. 7[E] G is directed to persons that register with the subject or investigator site based on a contact with a pharmaceutical call center; [Fig. 7F] Figs. 7H and 7J are [is] directed to persons that register with the subject or investigator site based on a *contact* with an

off-line call center and Fig. 7[G] J is directed to persons that register with the subject or investigator site based on a visit to a third party on-line recruitment site.

Page 31, lines 11-15

Referring now to [Figure 8] Figures 8A and 8B, there is shown a flow diagram of a process that may be used by a sponsor to accomplish the steps necessary to start a clinical study. The process may begin at two different points. Specifically, if the sponsor wishes to begin by making a feasibility assessment with respect to the study, the process starts at step 804. Alternatively, if the sponsor does not wish to make a feasibility assessment, the process starts at step 811.

Page 33, line 15 to page 34, line 8

The sponsor reaches step 811 either as an entry point into the process, or after the sponsor has determined in step 810 that the study is feasible. In step 811, tile sponsor determines whether the sponsor desires to use the investigator database to perform investigator recruitment for the study. If the sponsor wishes to use the investigator database for investigator recruitment, then in step 815, the sponsor begins by entering study parameter information into the system. A screen shot of a web page that may be used for entering this information is shown in [Figure 9] Figures 9A and 9B. In this step, the sponsor enters various parameters about the study into the system. Next, in step 816, the sponsor enters investigator search criteria for the study into the system. Such search criteria could include, for example, one or more specialties that would be desirable for an investigator for the study, information about the prescribing behavior of the investigator, the number of studies that the investigator has conducted, the therapeutic area and disease indication associated with clinical studies previously conducted by the investigator, the distance around the investigator site in which subjects participating in the study should be

sought, and the geographic area in which the investigator should be located. [Figure 10] Figures 10A and 10B depict [is] a screen shot of an exemplary web page that may be used by a sponsor to input the investigator search criteria into the system. In step 818, the sponsor is given the ability to weigh[t] one or more of the investigator criteria prior to initiating the investigator search.

Page 34, line 18 to page 35, line 8

An exemplary web page that shows the results of an investigator search in accordance with the present invention is shown in [Fig. 11] Figs. 11A and 11B. As shown in that figure, for each investigator identified in the search, the sponsor is shown the name of the investigator, the investigator's specialty, the city/state in which the investigator is located, the number of studies that the investigator has performed, subject demographic information obtained from the TIA database (i.e. the number of persons listed in the TIA database that are within a predetermined distance of the investigator site and who could potentially qualify as subjects for the clinical study), subject demographic information obtained from the subject database (i. e., the number of subjects listed in the subject database that are within a predetermined distance of the investigator site and who could potentially qualify to participate in the clinical study), the drug prescribing behavior of the investigator (e.g., the drug class prescribing decile associated with the investigator). It will be understood by those skilled in the art that other criteria relevant to the investigator could also be shown on this search results screen including for example, the behavior of the investigator with respect to ordering of laboratory tests/procedures.

Page 36, line 22 to page 37, line 19

After a potential subject has been identifies (step 817 or 819), the process of pre-screening for participation in the study begins (step 824). In this step, subjects *identifies* using

on-line and/or offline recruitment are notified, and asked whether or not they have an interest in participating in the clinical study. In the case of candidates that were identified on-line using the subject database, the subjects are preferably contacted by the means that they identified during their registration, on the subject site (e.g., by electronic mail) in order to preliminarily determine whether they have an interest in participating in the clinical study. A screen shot of an exemplary e-mail used for providing such a notification to a potential subject is shown in Fig. 14. The notification could alternatively be provided using telephone, mail, fax or any off line communication means. If a potential subject responds to a notification by indicating interest in participating in a clinical study, the subject is provided with a formal questionnaire that asks for information specifically relevant to the clinical study. An exemplary study-specific subject questionnaire is shown in reference to Figs. 15A – 15[F] H. In the preferred embodiment, if in response to the e-mail notification shown in Fig. 14, the subject indicates interest in participating in the clinical study, a study-specific subject questionnaire such as shown in Figs. 15A- 15[F] H is provided to the subject on a secure web page found on the subject site. The subject then uses this secure web page to answer all of the questions in the subject questionnaire, and to submit such answers for consideration. As mentioned above, irrespective of whether the subject is ultimately selected for participation in the clinical study, these questionnaire answers are stored in the subject database with the consent of the patient, thereby enriching the subject information stored in that database.

Page 39 lines 2-7

Fig. 16 is a process flow diagram of a method for identifying eligible investigators for a clinical study in accordance with one embodiment of the present invention. Specifically, at step 1610, information is stored in database 2200 of the inventive system (in particular, the data is

stored in table 2252, field 2252a of Fig. 22[B] E) relating to the geographic location of each of a plurality of investigators. At step 1620, an incidence or a prevalence of each of a plurality of disease conditions in a plurality of different geographic locations is stored in the database.

Page 46 lines 13-18

At step [2140] 2141, information is stored in the database that associates the types of equipment that an investigator has with one or more disease condition[s]. At step [2141] 2142, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related equipment that an investigator has. At step [2142] 2143 the inventive system identifies an investigator based upon the query results and the investigator's equipment.

Page 46 line 19 to page 47, line 2

Fig. 21L is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2143', information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator practice setting, which is where the actual clinical study is conducted, and where a subject would most likely go to participate. 'this information is provided by the investigator.

Page 59, line 15 to page 60 line 2

Fig. 22A through 22[F] K is an exemplary data structure for implementing an investigator database 2200. For example, table 2210 includes investigator data related to basics such as name, age, address, phone, etc. Table 2220 contains data about a specific study performed by the investigator, Table 2230 relates to the investigator's specialties, and Table 2240 relates to the

investigator's subject population. Shown in [Fig. 22B] Figs. 22C and 22E, table 2250 contains data about the investigator's staff. Table 2260 of Fig. 22[C] F contains data regarding the investigator's hospital affiliations. It will be understood by those skilled in the art that the investigator database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Figs. 22A thorough 22[F] K represents one example of such a data structure.

Page 60, lines 4-20

Figs. 22[G-K] L-P depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection. The example shown relates specifically to use of the invention to perform a study related to the disease of angina. Initially, the TIA database is queried using angina as the query criterion to identify geographic locations where the incidence of angina is more prevalent. These areas are identified on a national basis in Fig. 22[G] L, and specifically for the Dallas-Fort Worth area in Fig. 22[H] M. It bears noting that, within the Dallas-Fort Worth area, the TIA database IMS further identified an incidence value for each sub-region of the Dallas-Fort Worth area. Sites of various investigators in Dallas-Fort Worth that are potentially eligible to perform the study are also shown on Fig. 22[H] M. These investigator sites were found by querying the investigator database as described above. Fig. 22[1] N shows that there are three eligible investigator sites in the Dallas-Fort Worth Area. These three investigator sites are shown as circled stars in Fig. 22[1] N. Of the three eligible investigator sites, one of the investigator sites is located in a sub-region having a higher incidence of angina than is found in the sub-regions of the other two eligible investigators. As shown in Fig. 22[J] O, the investigator located in the sub-region having the highest incidence of angina is next selected to perform the study. Following selection of this investigator for the

study, subjects closest to the site of the selected investigator are identified for screening, as shown in Fig. 22[K] P.

Page 61, lines 12-15

Fig. 23 is a screen shot showing sponsor access limitations to study data. Aggregated data 2302 can be viewed by all sponsors, whereas data 2304 can only be viewed by the sponsor that supplied that data 2304 to the database. [Fig. 26] Figs. 26A and 26B depict[s] an exemplary data structure used for implementing the sponsor access limitations discussed above.

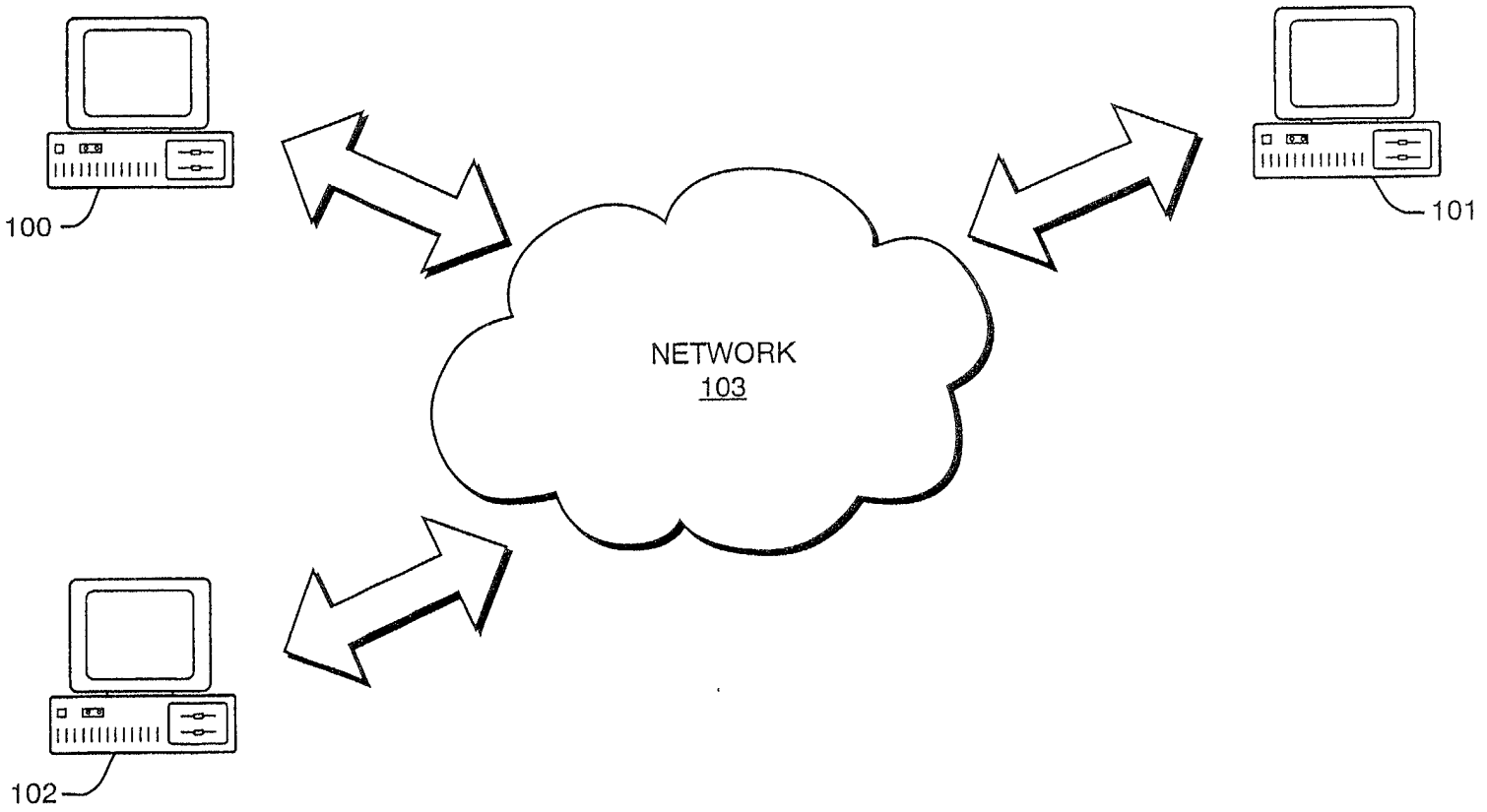

FIG. 1A

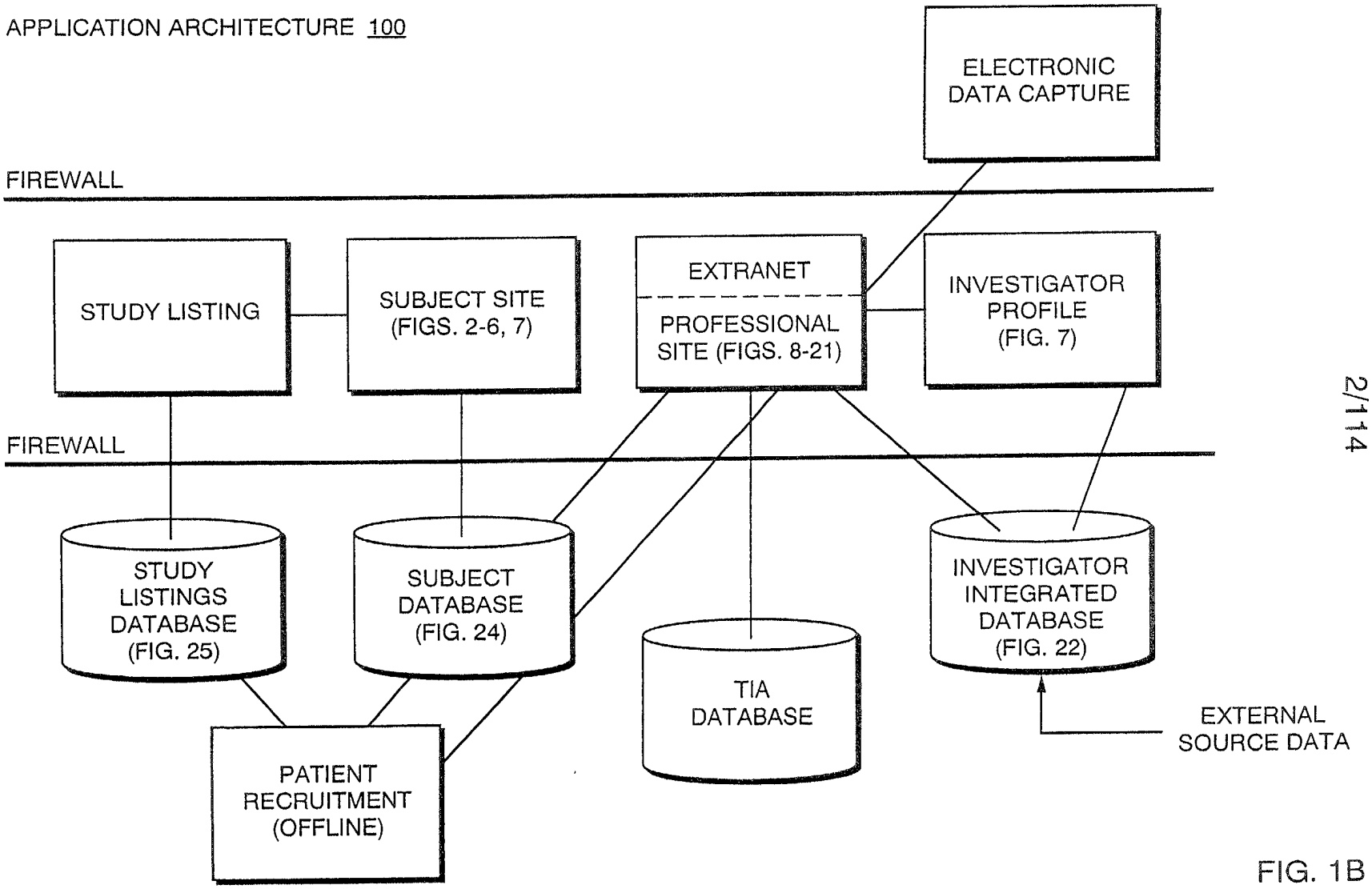
APPLICATION ARCHITECTURE 100
ELECTRONIC DATA CAPTURE
FIREWALL
STUDY LISTING
SUBJECT SITE (FIGS. 2-6, 7)
EXTRANET
PROFESSIONAL SITE (FIGS. 8-21)
INVESTIGATOR PROFILE (FIG. 7)
FIREWALL
STUDY LISTINGS DATABASE (FIG. 25)
SUBJECT DATABASE (FIG. 24)
TIA DATABASE
INVESTIGATOR INTEGRATED DATABASE (FIG. 22)
EXTERNAL SOURCE DATA
PATIENT RECRUITMENT (OFFLINE)

FIG. 1B

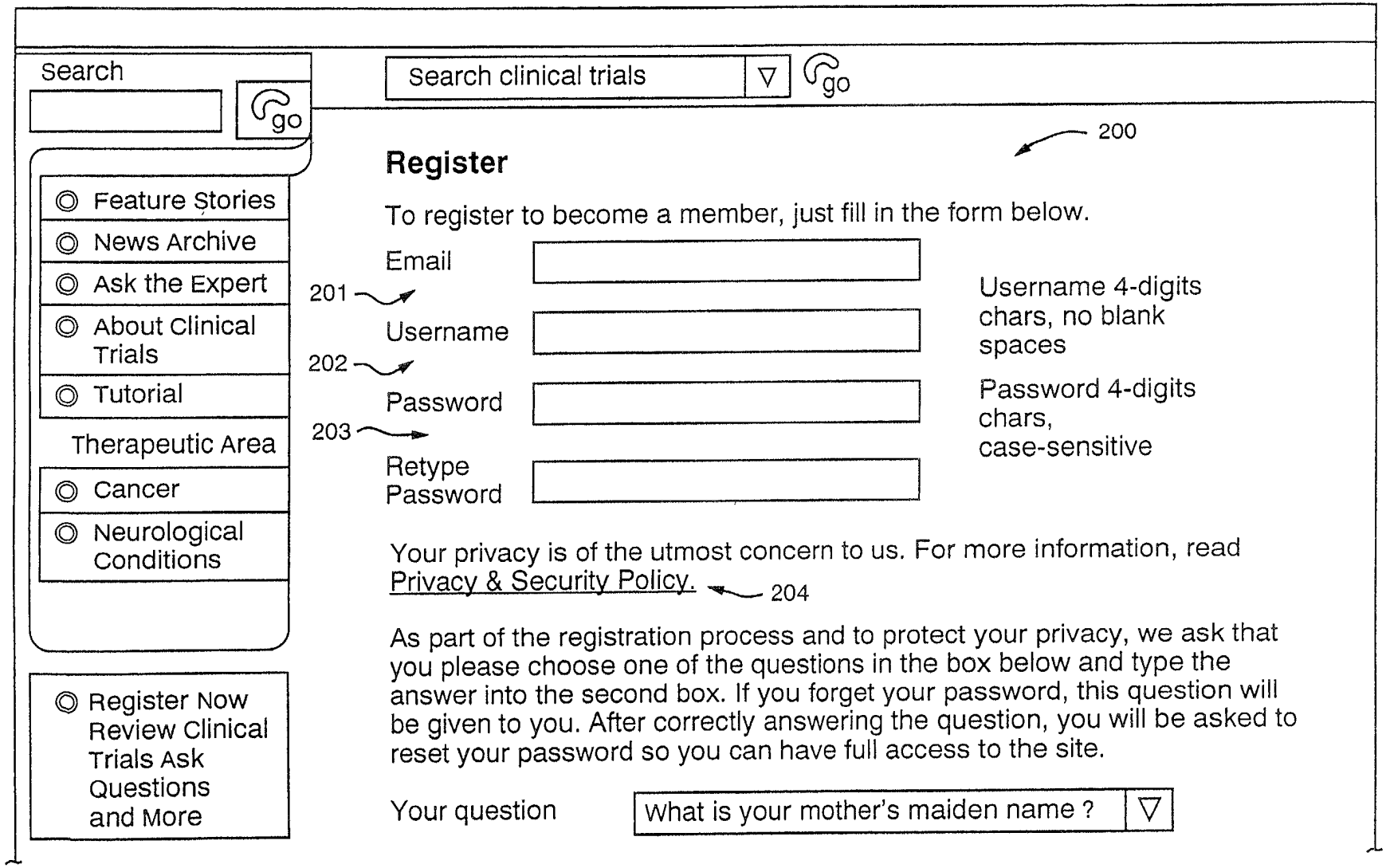
Search
go
Search clinical trials
go
200
Register
To register to become a member, just fill in the form below.
Email
201
Username
202
Password
203
Retype Password
Username 4-digits chars, no blank spaces
Password 4-digits chars, case-sensitive
Your privacy is of the utmost concern to us. For more information, read Privacy & Security Policy.
204
As part of the registration process and to protect your privacy, we ask that you please choose one of the questions in the box below and type the answer into the second box. If you forget your password, this question will be given to you. After correctly answering the question, you will be asked to reset your password so you can have full access to the site.
Your question
What is your mother's maiden name ?
Feature Stories
News Archive
Ask the Expert
About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More

FIG. 2A

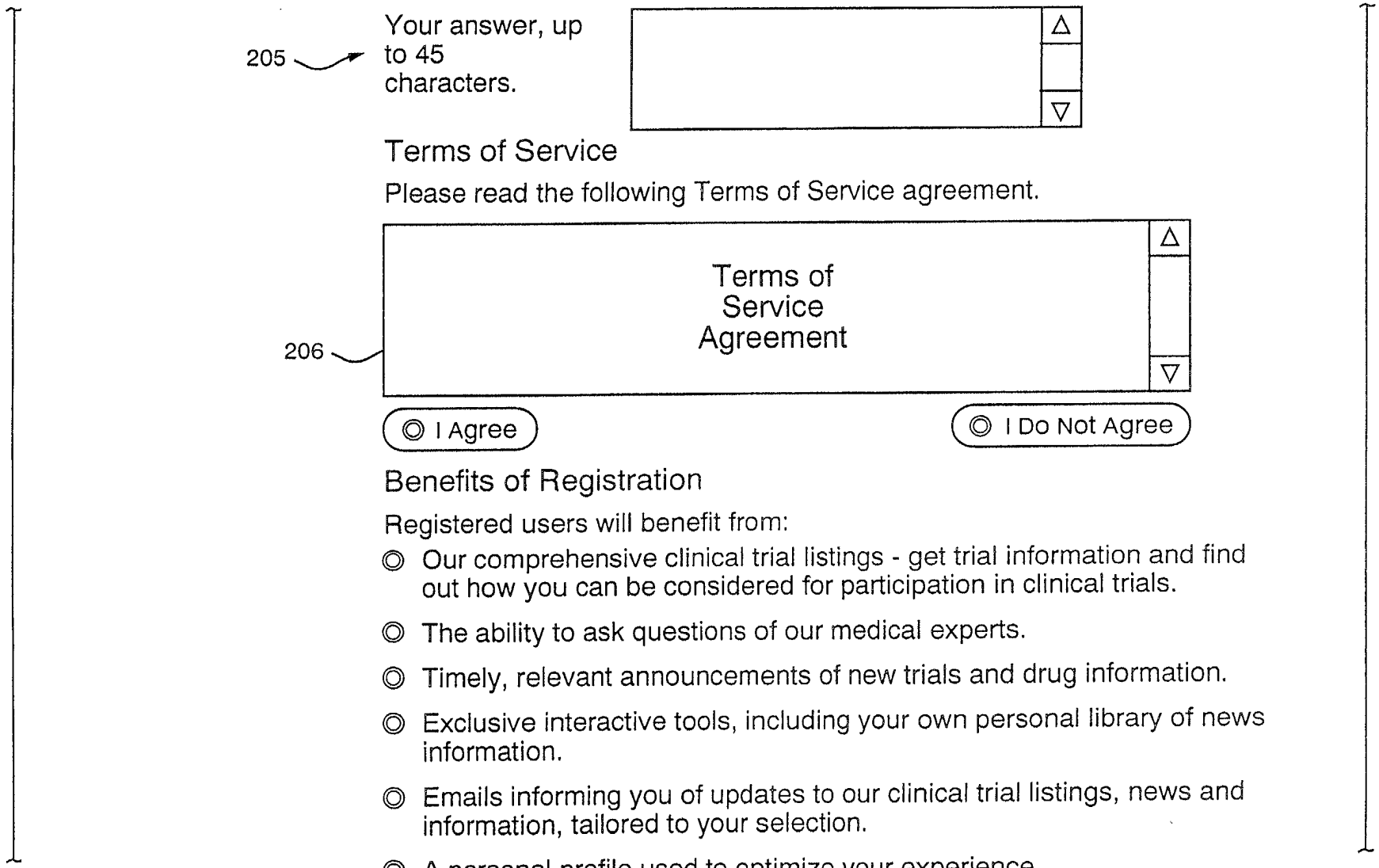
205
Your answer, up to 45 characters.
Terms of Service
Please read the following Terms of Service agreement.
206
Terms of Service Agreement
I Agree
I Do Not Agree
Benefits of Registration
Registered users will benefit from:
Our comprehensive clinical trial listings - get trial information and find out how you can be considered for participation in clinical trials.
The ability to ask questions of our medical experts.
Timely, relevant announcements of new trials and drug information.
Exclusive interactive tools, including your own personal library of news information.
Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection.
A personal profile used to optimize your experience.

FIG. 2B

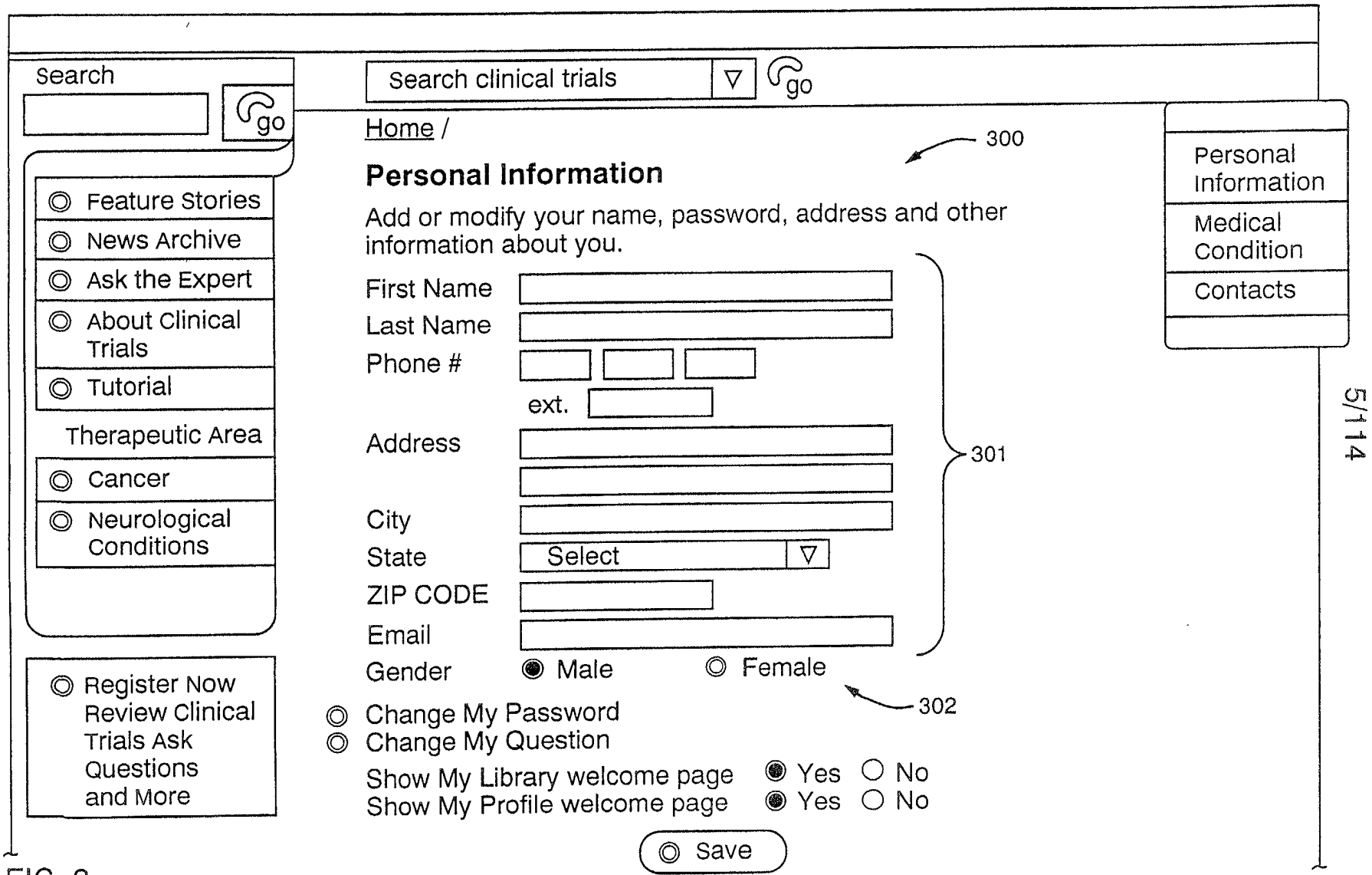
Search
go
Search clinical trials
go
Home /
300
Personal Information
Add or modify your name, password, address and other information about you.
First Name
Last Name
Phone #
ext.
Address
City
State
Select
ZIP CODE
Email
Gender
Male
Female
301
302
Change My Password
Change My Question
Show My Library welcome page
Yes
No
Show My Profile welcome page
Yes
No
Save
Feature Stories
News Archive
Ask the Expert
About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Personal Information
Medical Condition
Contacts

FIG. 3

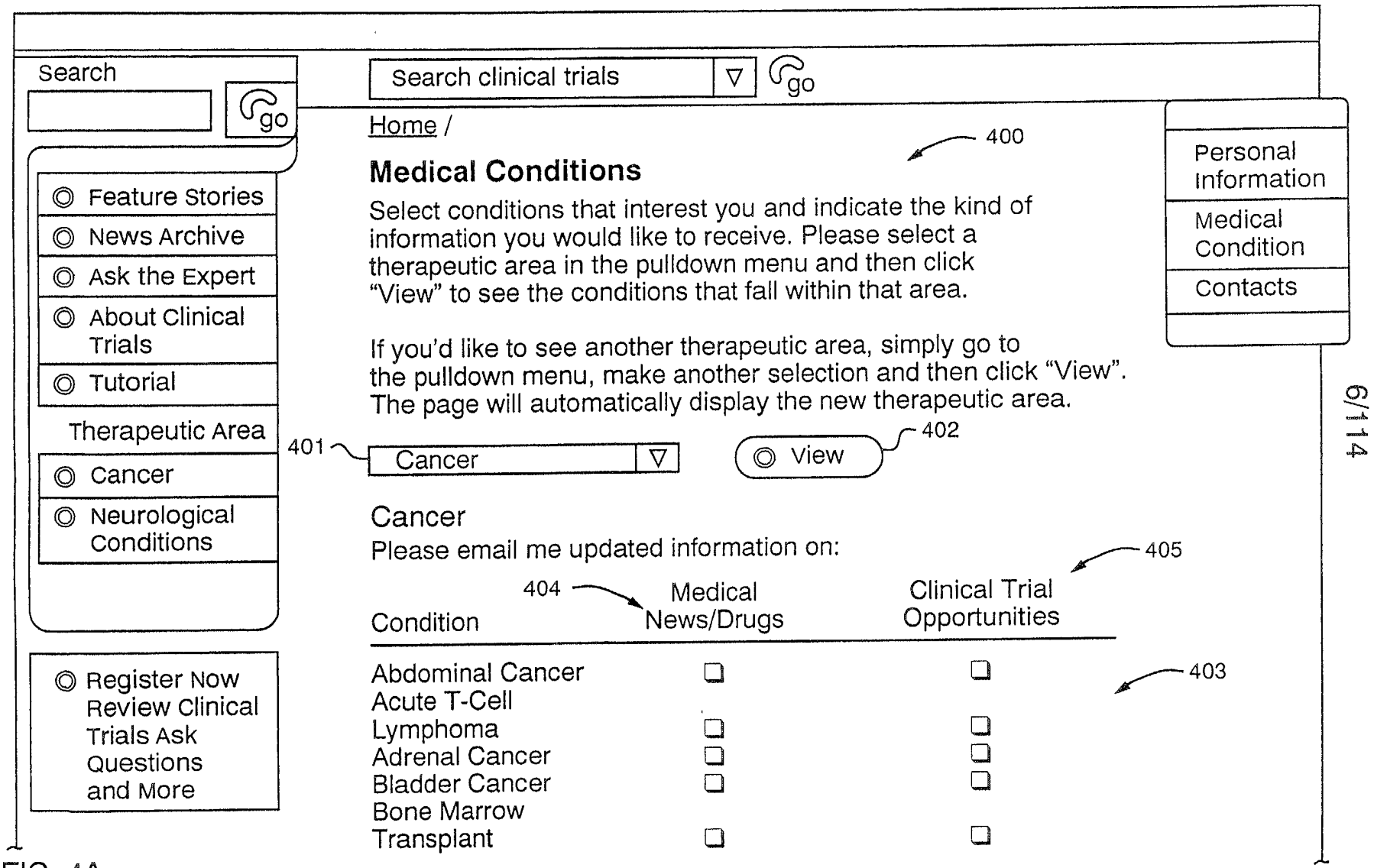
Search
go
Search clinical trials
go
Home /
400
Medical Conditions
Select conditions that interest you and indicate the kind of information you would like to receive. Please select a therapeutic area in the pulldown menu and then click "View" to see the conditions that fall within that area.
If you'd like to see another therapeutic area, simply go to the pulldown menu, make another selection and then click "View". The page will automatically display the new therapeutic area.
Personal Information
Medical Condition
Contacts
Feature Stories
News Archive
Ask the Expert
About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
401
Cancer
View
402
Cancer
Please email me updated information on:
405
404
Condition
Medical News/Drugs
Clinical Trial Opportunities
403
Abdominal Cancer
Acute T-Cell Lymphoma
Adrenal Cancer
Bladder Cancer
Bone Marrow Transplant
Register Now Review Clinical Trials Ask Questions and More

FIG. 4A

Bone Metastases	☐	☐
Brain Cancer	☐	☐
Breast Cancer	☐	☐
Cancer Pain	☐	☐
Cancer/Tumors	☐	☐
Cervical Cancer	☐	☐
Cervical Neoplasia	☐	☐
Chemotherapy	☐	☐
Colon Malignancies	☐	☐
Colon Polyps	☐	☐
Colorectal Cancer	☐	☐
Effects of Chemotherapy	☐	☐
Endometrial Cancer	☐	☐
Esophageal Cancer	☐	☐
Fibrocystic Breast	☐	☐
Gall Bladder Cancer	☐	☐
Gastric Cancer	☐	☐
Gliomas	☐	☐
Head and Neck Cancer	☐	☐
Hepatoblastoma	☐	☐
Histiocytoma	☐	☐
Islet Cell Cancer	☐	☐
Kaposi's Sarcoma	☐	☐
Kidney Cancer	☐	☐

FIG. 4B

Leukemia	❑	❑
Liver Cancer	❑	❑
Lung Cancer	❑	❑
Lymphomas	❑	❑
Malignant Adenoma	❑	❑
Malignant Melanoma	❑	❑
Medical Prosthetics	❑	❑
Meningiomas	❑	❑
Mesothelioma	❑	❑
Metastatic Cancer	❑	❑
Multiple Myelomas	❑	❑
Mycosis Fungoides	❑	❑
Neoplasms	❑	❑
Neurectoderma	❑	❑
Neuroblastoma	❑	❑
Neurofibromatosis	❑	❑
Non-Hodgkin's Lymphoma	❑	❑
Oral Cavity Cancer	❑	❑
Ovarian Cancer	❑	❑
Pancreatic Cancer	❑	❑
Pelvic Cancer	❑	❑
Platelet Deficiencies	❑	❑
Prostate Cancer	❑	❑

FIG. 4C

Rectal Cancer	❑	❑
Renal Cell Carcinoma	❑	❑
Sarcoma	❑	❑
Skin Cancer	❑	❑
Spinal Cord Malignancy	❑	❑
Stomach Cancer	❑	❑
T-Cell Lymphoma	❑	❑
Testicular Cancer	❑	❑
Thrombocytopenia	❑	❑
Thymomas	❑	❑
Vaginal Cancer	❑	❑
Vulvar Carcinoma	❑	❑
Wilms' Tumor	❑	❑

◎ Save

FIG. 4D

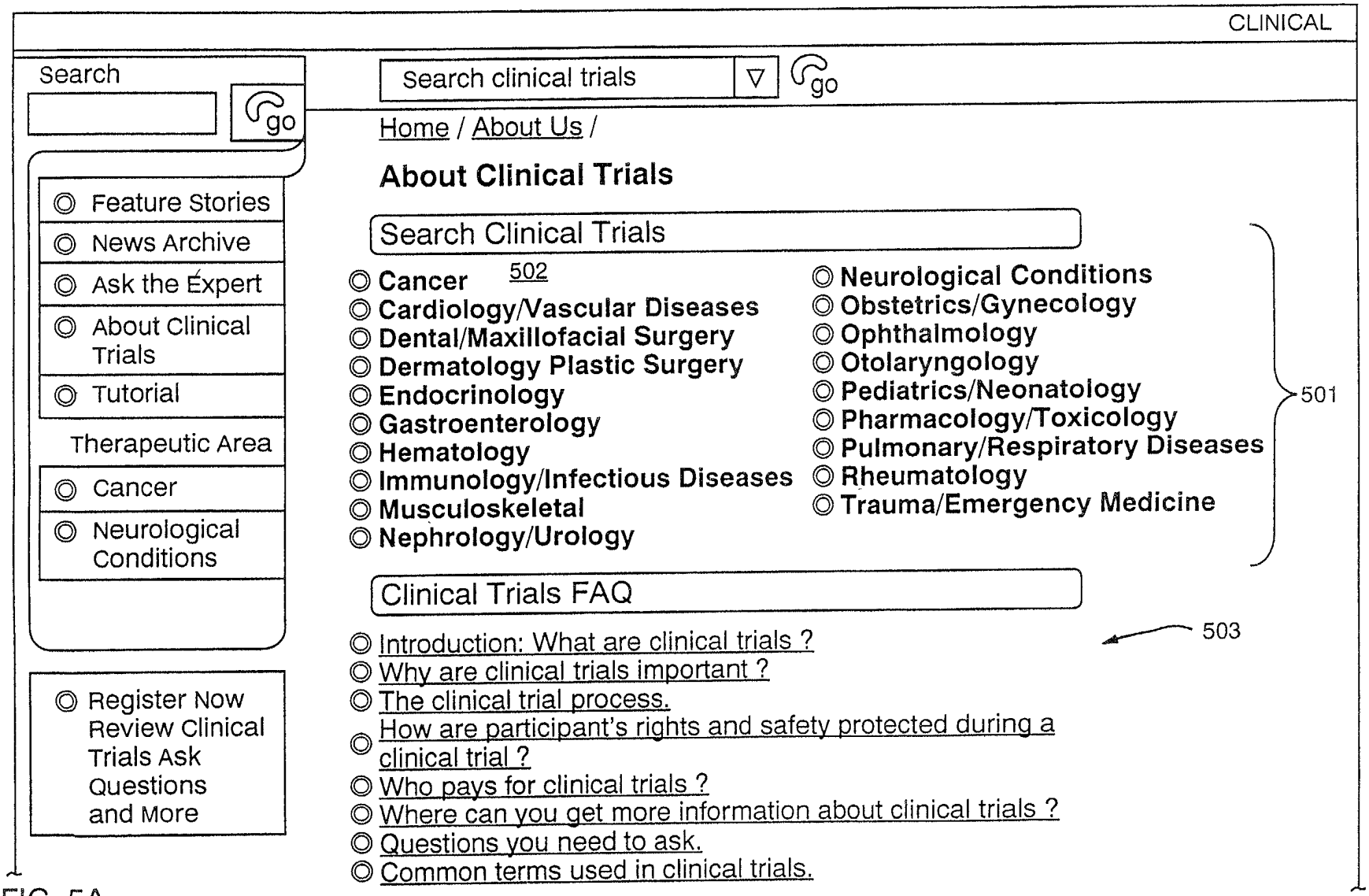
CLINICAL
Search
go
Search clinical trials
go
Home / About Us /
About Clinical Trials
Feature Stories
News Archive
Ask the Expert
About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More
Search Clinical Trials
502
Cancer
Cardiology/Vascular Diseases
Dental/Maxillofacial Surgery
Dermatology Plastic Surgery
Endocrinology
Gastroenterology
Hematology
Immunology/Infectious Diseases
Musculoskeletal
Nephrology/Urology
Neurological Conditions
Obstetrics/Gynecology
Ophthalmology
Otolaryngology
Pediatrics/Neonatology
Pharmacology/Toxicology
Pulmonary/Respiratory Diseases
Rheumatology
Trauma/Emergency Medicine
501
Clinical Trials FAQ
503
Introduction: What are clinical trials ?
Why are clinical trials important ?
The clinical trial process.
How are participant's rights and safety protected during a clinical trial ?
Who pays for clinical trials ?
Where can you get more information about clinical trials ?
Questions you need to ask.
Common terms used in clinical trials.

FIG. 5A

Introduction: What are clinical trials ?

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Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

FIG. 5B

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If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

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Why are clinical trials important ?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

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The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

FIG. 5C

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

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Phase II. In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

Phase III. In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

Phase IV. Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

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FIG. 5D

How are participant's rights and safety protected during a clinical trial ?

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The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

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Who pays for clinical trials ?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.

FIG. 5E

- Sponsors may pay you to participate in a clinical trial. Typically, these fees, when provided, are nominal. 503
- Medical care is often provided at no cost to the patients, but they still may be responsible for other expenses such as travel between their homes and the health care facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

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Where can you get more information about clinical trials ?

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your health care provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

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FIG. 5F

Questions you need to ask. 503

- What is the length of your involvement in the clinical trial ? How long will the trial last ?
- Where will you have to go in order to participate in the clinical trial ?
- What are the possible treatments you may receive while in the clinical trial ?
- Do the treatment alternatives they provide cover all possible treatments for this disease ? If not, what are your other treatment alternatives ?
- What procedures are built into the study to keep you safe from harm while you are participating ?
- What are the risks and benefits of participating in the clinical trial ?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study ?
- What costs may you incur if you participate ?
- Will the treatment be available to you even after the clinical trial has concluded ?
- Where are the funds coming from to conduct this trial ? What is their purpose in sponsoring the trial ?

You should also feel free to ask any other question about the trial you want answered.

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FIG. 5G

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Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

FIG. 5H

503

Informed Consent: Informed consent is a process that confirms a patient understands the nature of a study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

Principal investigator: The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

Protocol: A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

FIG. 5I

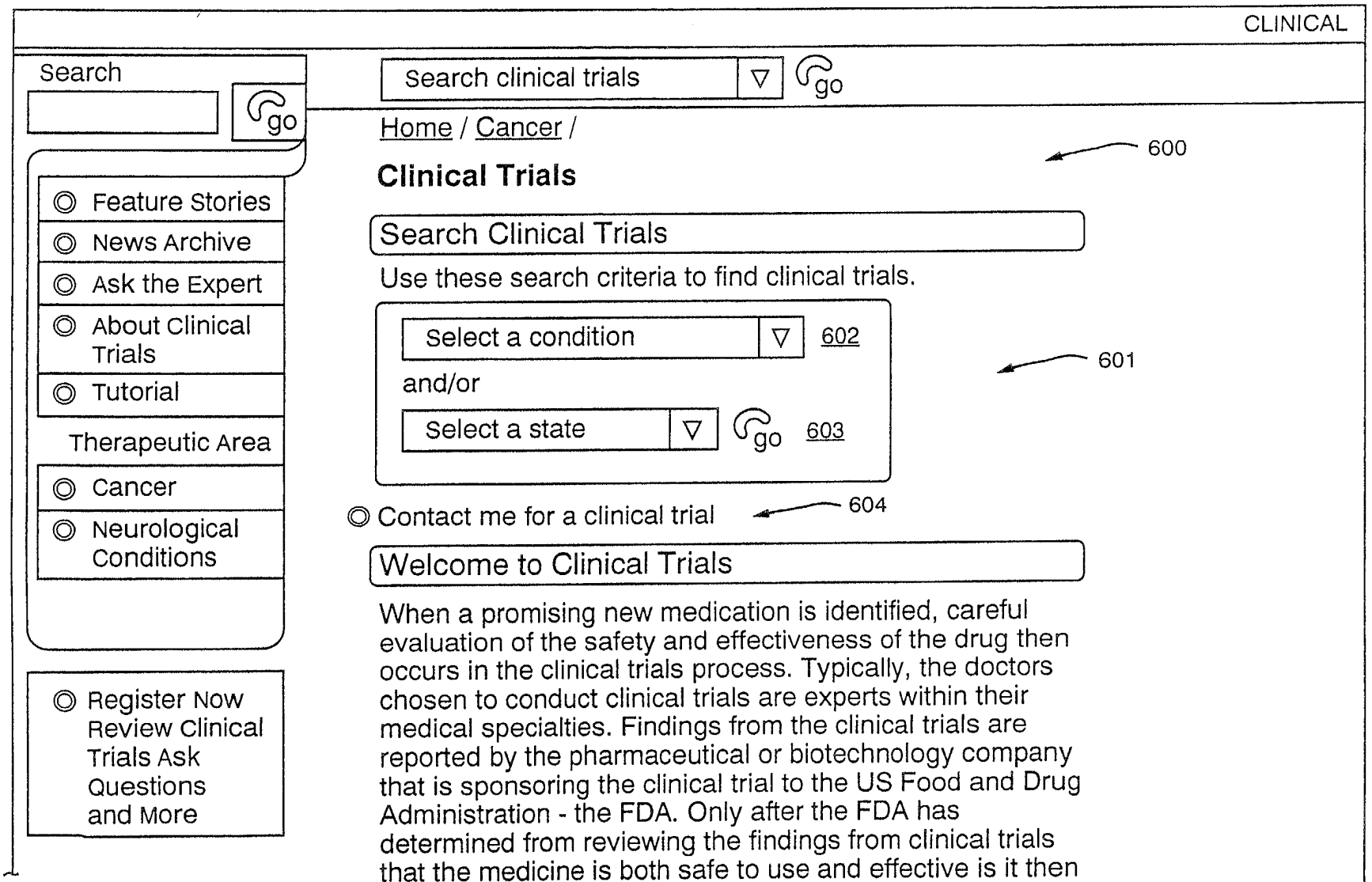
503

Sponsor: The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the "best treatment" currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

◎ Back to top

FIG. 5J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600
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Therapeutic Area
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Select a condition
602
601
and/or
Select a state
go
603
Contact me for a clinical trial
604
Register Now Review Clinical Trials Ask Questions and More
Welcome to Clinical Trials
When a promising new medication is identified, careful evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration - the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then

FIG. 6A

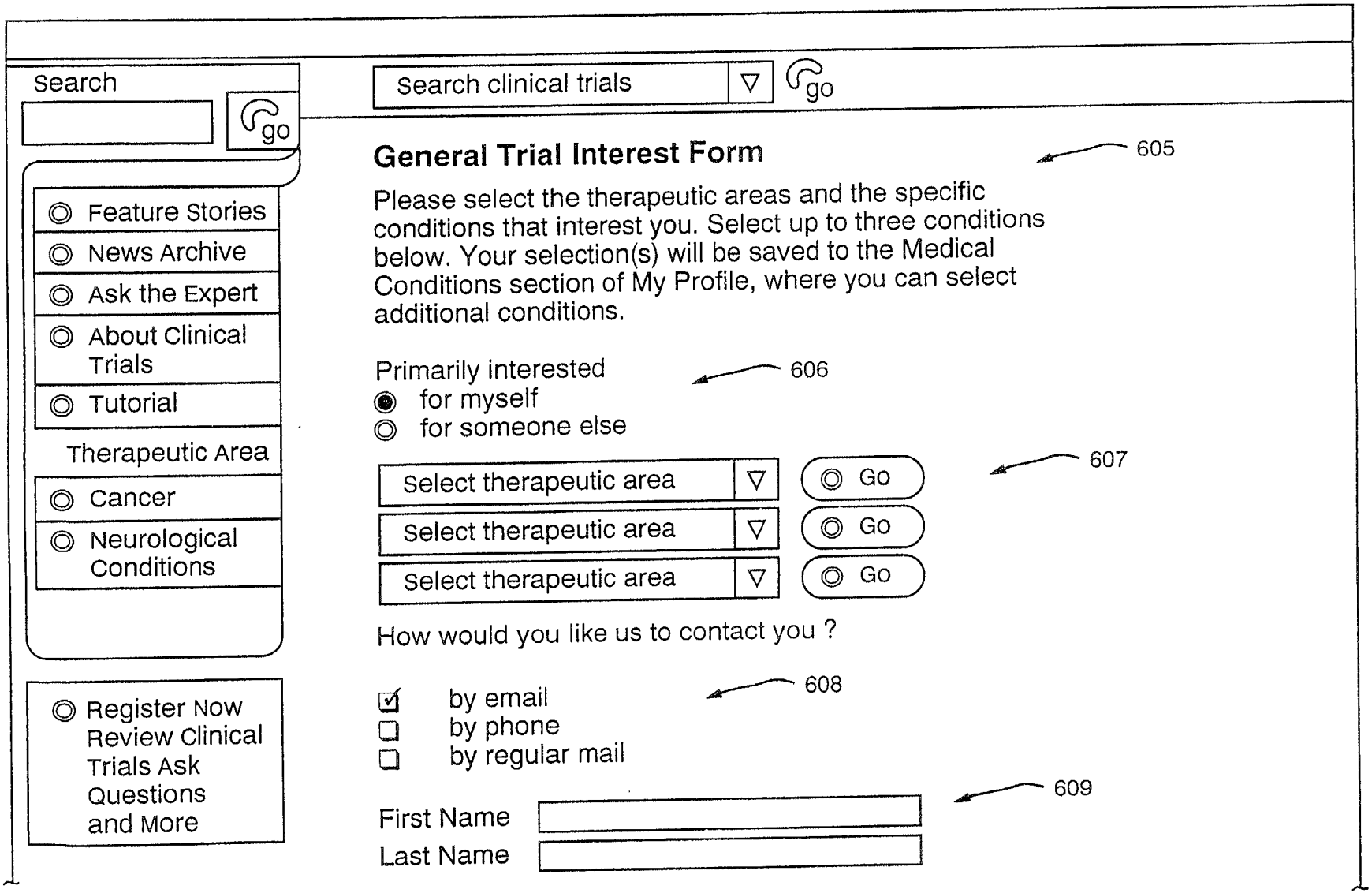
made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

FIG. 6B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Neurological Conditions
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Search clinical trials
go
General Trial Interest Form
605
Please select the therapeutic areas and the specific conditions that interest you. Select up to three conditions below. Your selection(s) will be saved to the Medical Conditions section of My Profile, where you can select additional conditions.
Primarily interested
606
for myself
for someone else
Select therapeutic area
Go
607
How would you like us to contact you ?
608
by email
by phone
by regular mail
609
First Name
Last Name

FIG. 6C

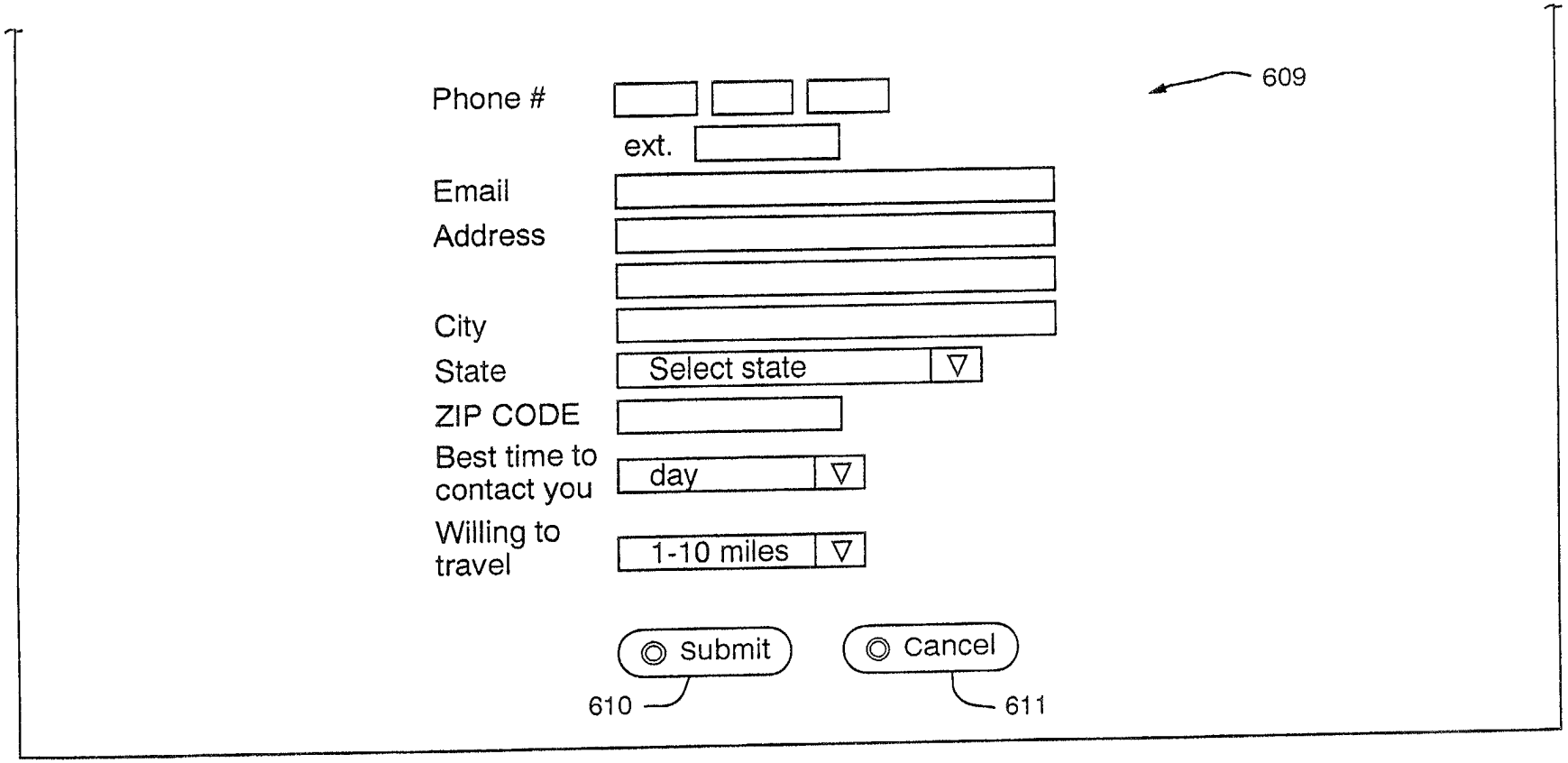
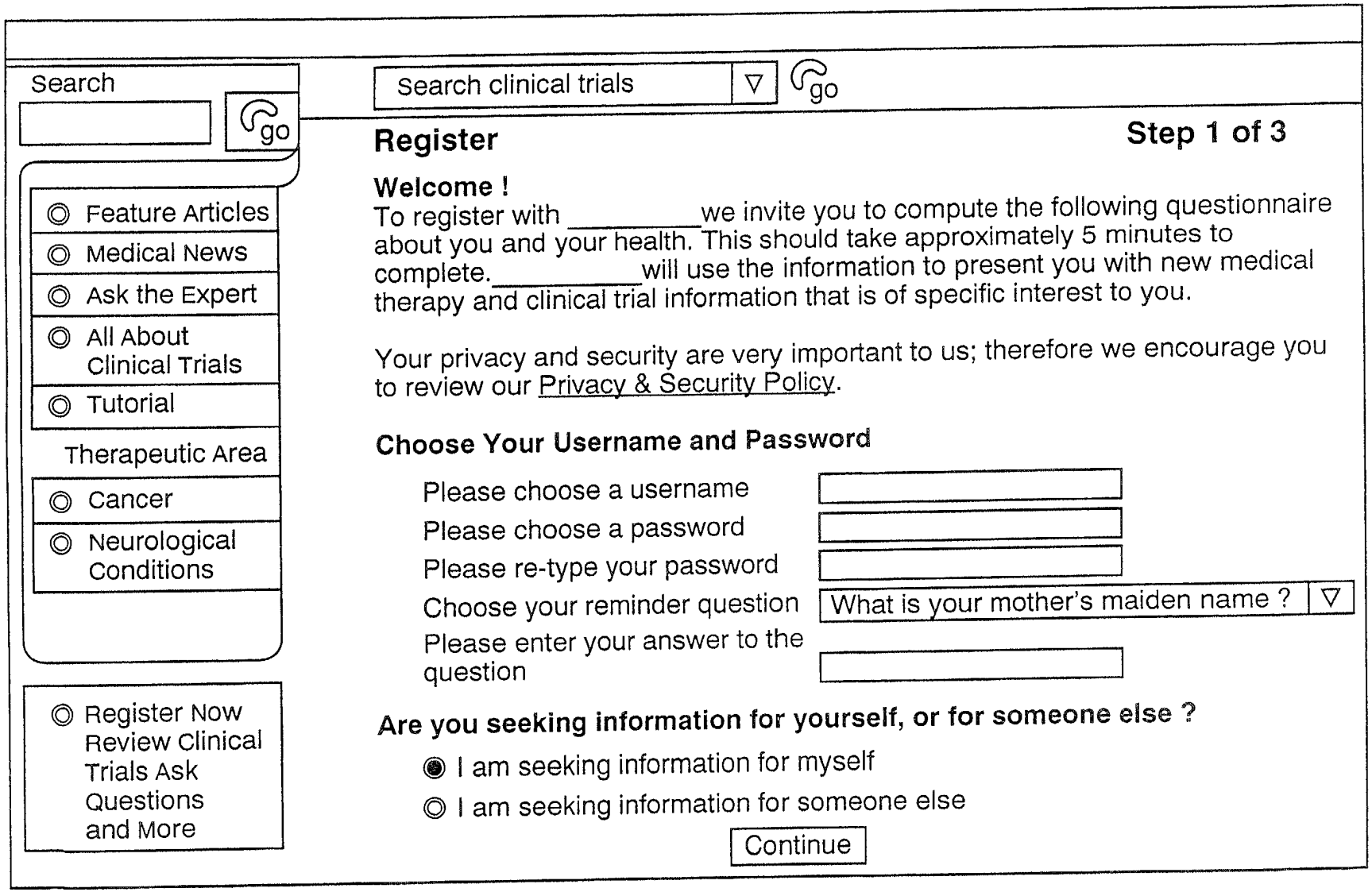

609
Phone #
ext.
Email
Address
City
State
Select state
ZIP CODE
Best time to contact you
day
Willing to travel
1-10 miles
Submit
Cancel
610
611

FIG. 6D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Cancer
Neurological Conditions
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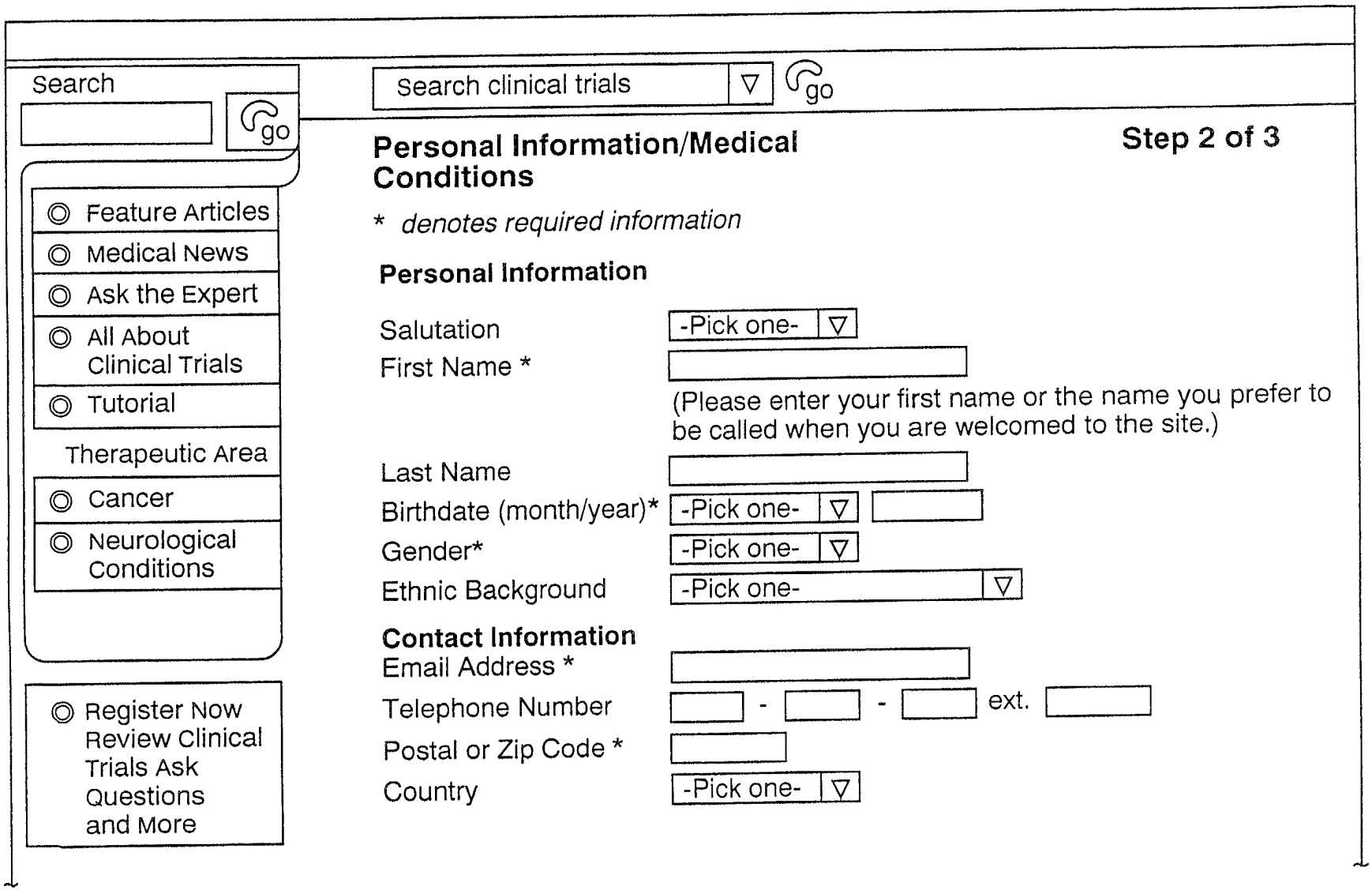
Search clinical trials
go
Register
Step 1 of 3
Welcome !
To register with _____we invite you to compute the following questionnaire about you and your health. This should take approximately 5 minutes to complete._____will use the information to present you with new medical therapy and clinical trial information that is of specific interest to you.
Your privacy and security are very important to us; therefore we encourage you to review our Privacy & Security Policy.
Choose Your Username and Password
Please choose a username
Please choose a password
Please re-type your password
Choose your reminder question
What is your mother's maiden name ?
Please enter your answer to the question
Are you seeking information for yourself, or for someone else ?
I am seeking information for myself
I am seeking information for someone else
Continue

FIG. 6E


Search
go
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go
Feature Articles
Medical News
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All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Personal Information/Medical Conditions
Step 2 of 3
* denotes required information
Personal Information
Salutation
-Pick one-
First Name *
(Please enter your first name or the name you prefer to be called when you are welcomed to the site.)
Last Name
Birthdate (month/year)*
-Pick one-
Gender*
-Pick one-
Ethnic Background
-Pick one-
Contact Information
Email Address *
Telephone Number
ext.
Postal or Zip Code *
Country
-Pick one-

FIG. 6F

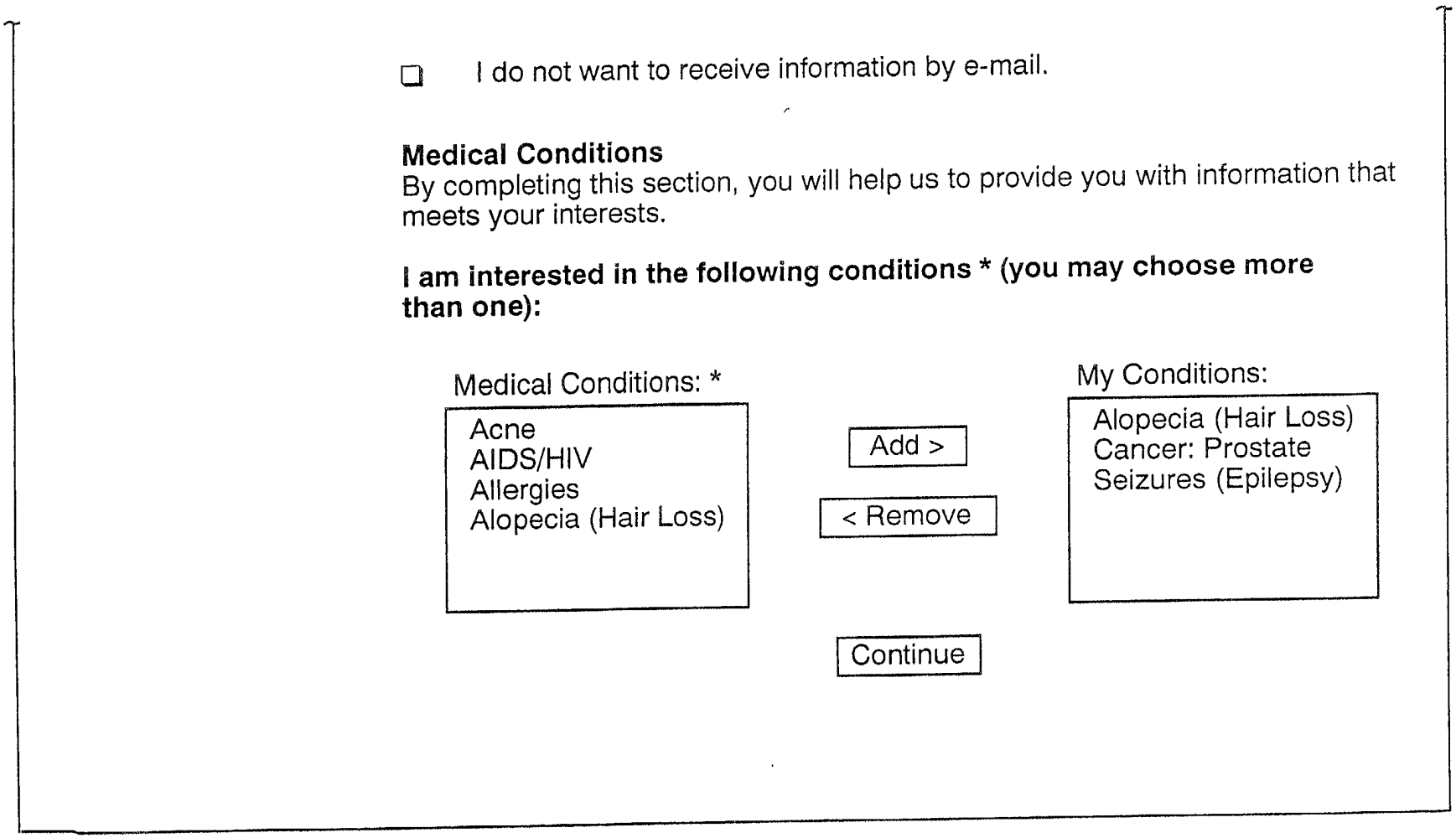
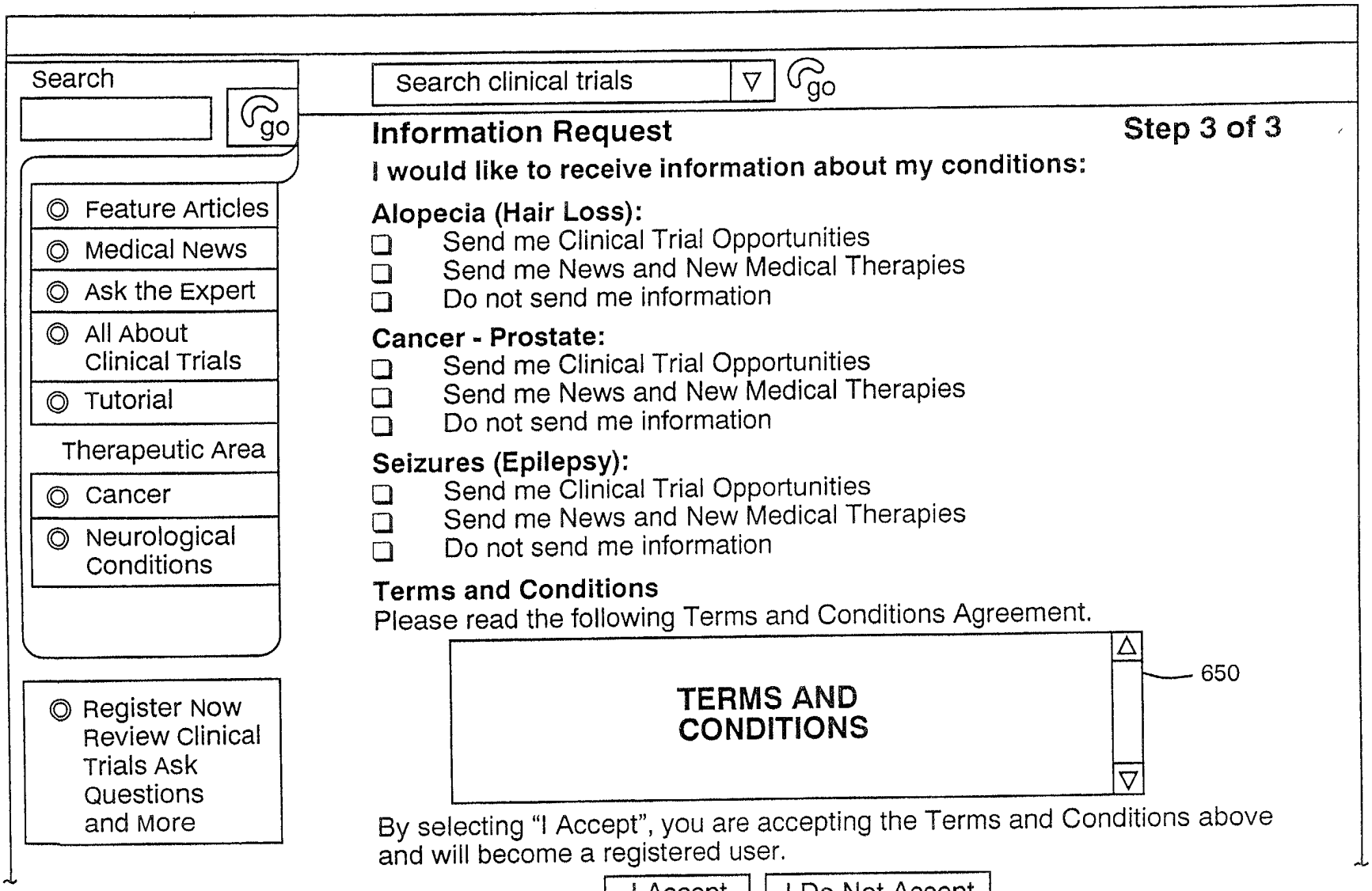

I do not want to receive information by e-mail.
Medical Conditions
By completing this section, you will help us to provide you with information that meets your interests.
I am interested in the following conditions * (you may choose more than one):
Medical Conditions: *
Acne
AIDS/HIV
Allergies
Alopecia (Hair Loss)
Add >
< Remove
My Conditions:
Alopecia (Hair Loss)
Cancer: Prostate
Seizures (Epilepsy)
Continue

FIG. 6G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go
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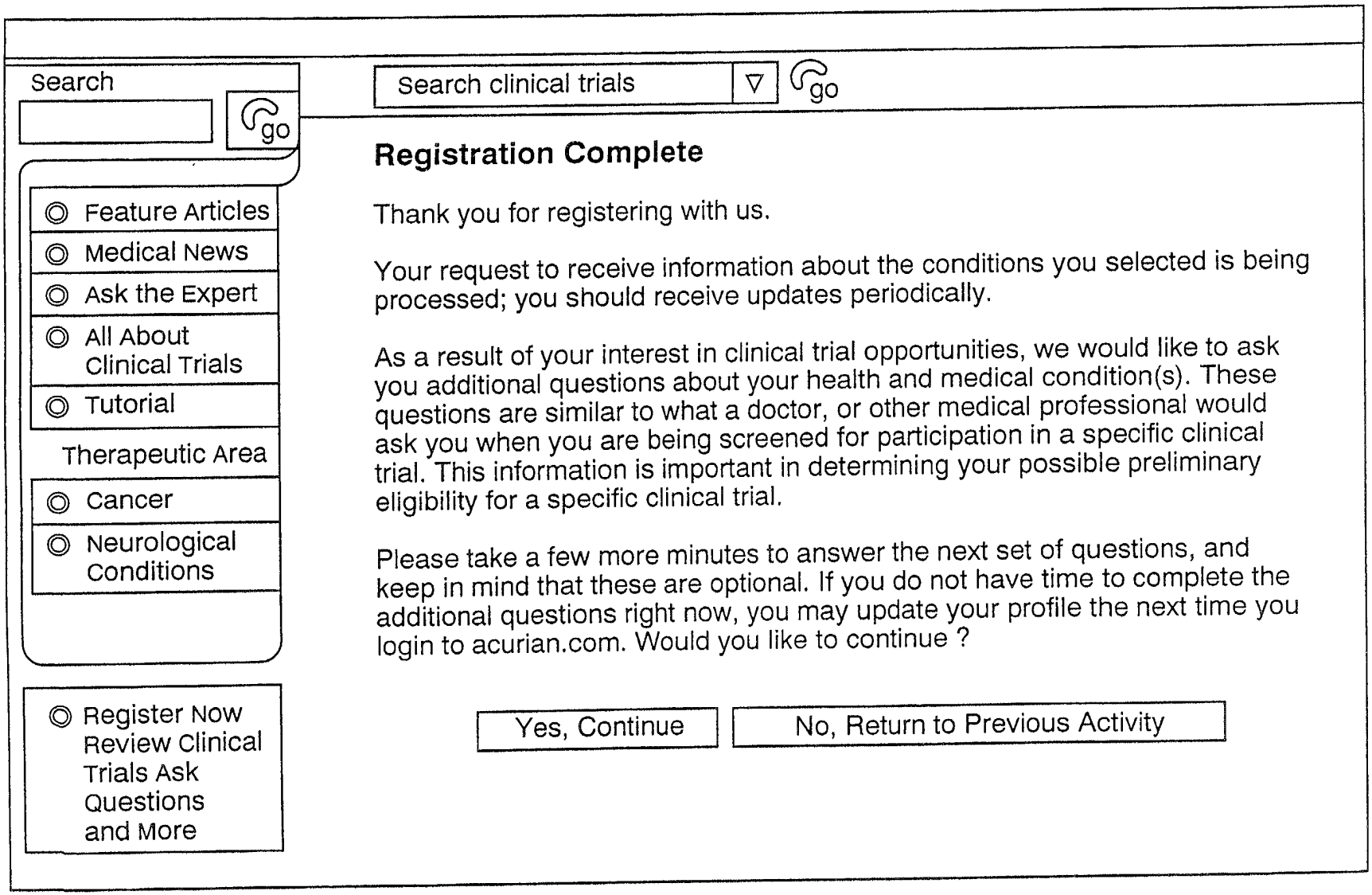
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Search clinical trials
go
Information Request
Step 3 of 3
I would like to receive information about my conditions:
Alopecia (Hair Loss):
Send me Clinical Trial Opportunities
Send me News and New Medical Therapies
Do not send me information
Cancer - Prostate:
Send me Clinical Trial Opportunities
Send me News and New Medical Therapies
Do not send me information
Seizures (Epilepsy):
Send me Clinical Trial Opportunities
Send me News and New Medical Therapies
Do not send me information
Terms and Conditions
Please read the following Terms and Conditions Agreement.
TERMS AND CONDITIONS
650
By selecting "I Accept", you are accepting the Terms and Conditions above and will become a registered user.
I Accept
I Do Not Accept

FIG. 6H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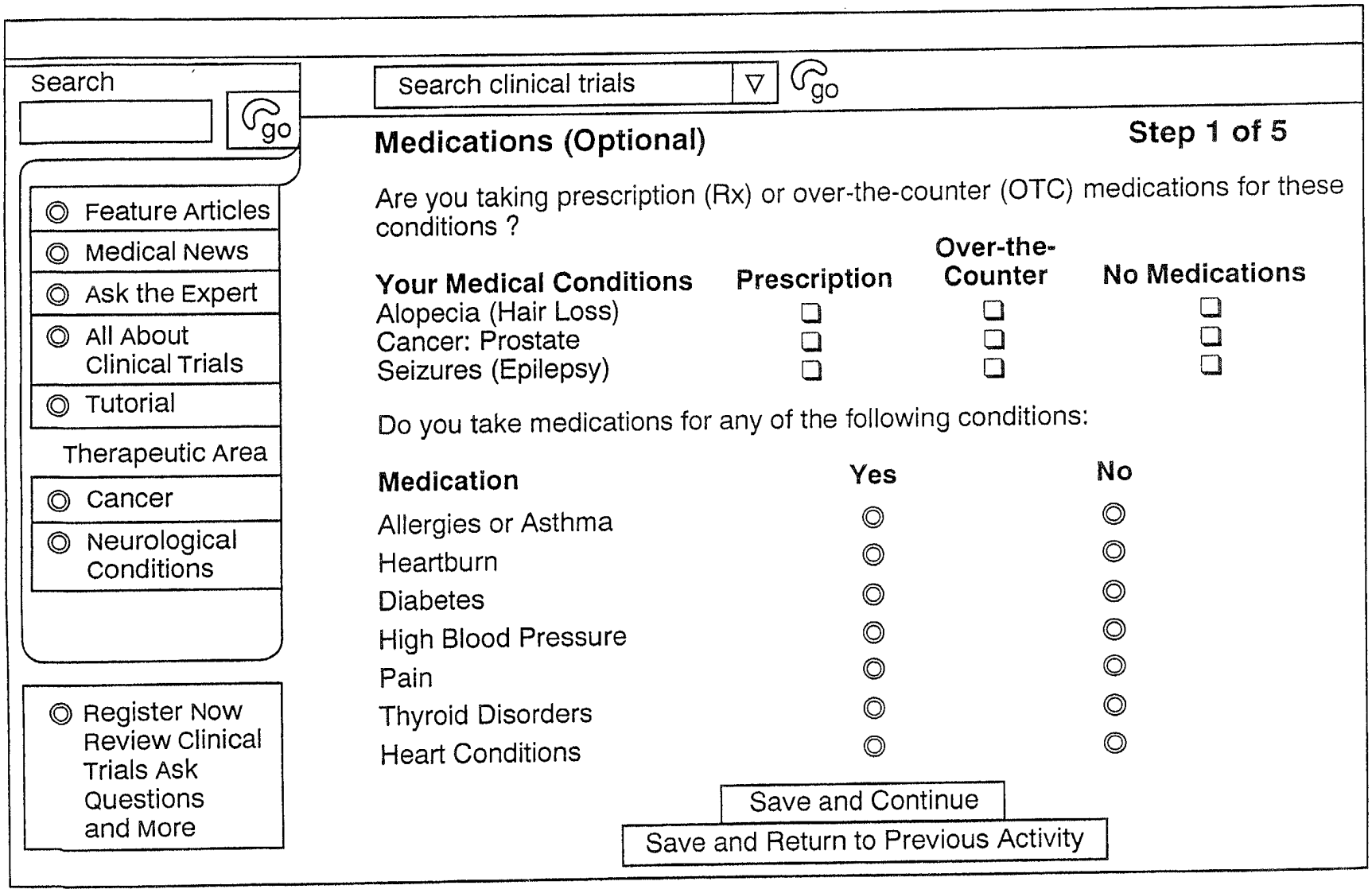
Search clinical trials
go
Registration Complete
Thank you for registering with us.
Your request to receive information about the conditions you selected is being processed; you should receive updates periodically.
As a result of your interest in clinical trial opportunities, we would like to ask you additional questions about your health and medical condition(s). These questions are similar to what a doctor, or other medical professional would ask you when you are being screened for participation in a specific clinical trial. This information is important in determining your possible preliminary eligibility for a specific clinical trial.
Please take a few more minutes to answer the next set of questions, and keep in mind that these are optional. If you do not have time to complete the additional questions right now, you may update your profile the next time you login to acurian.com. Would you like to continue ?
Yes, Continue
No, Return to Previous Activity

FIG. 6I


Search
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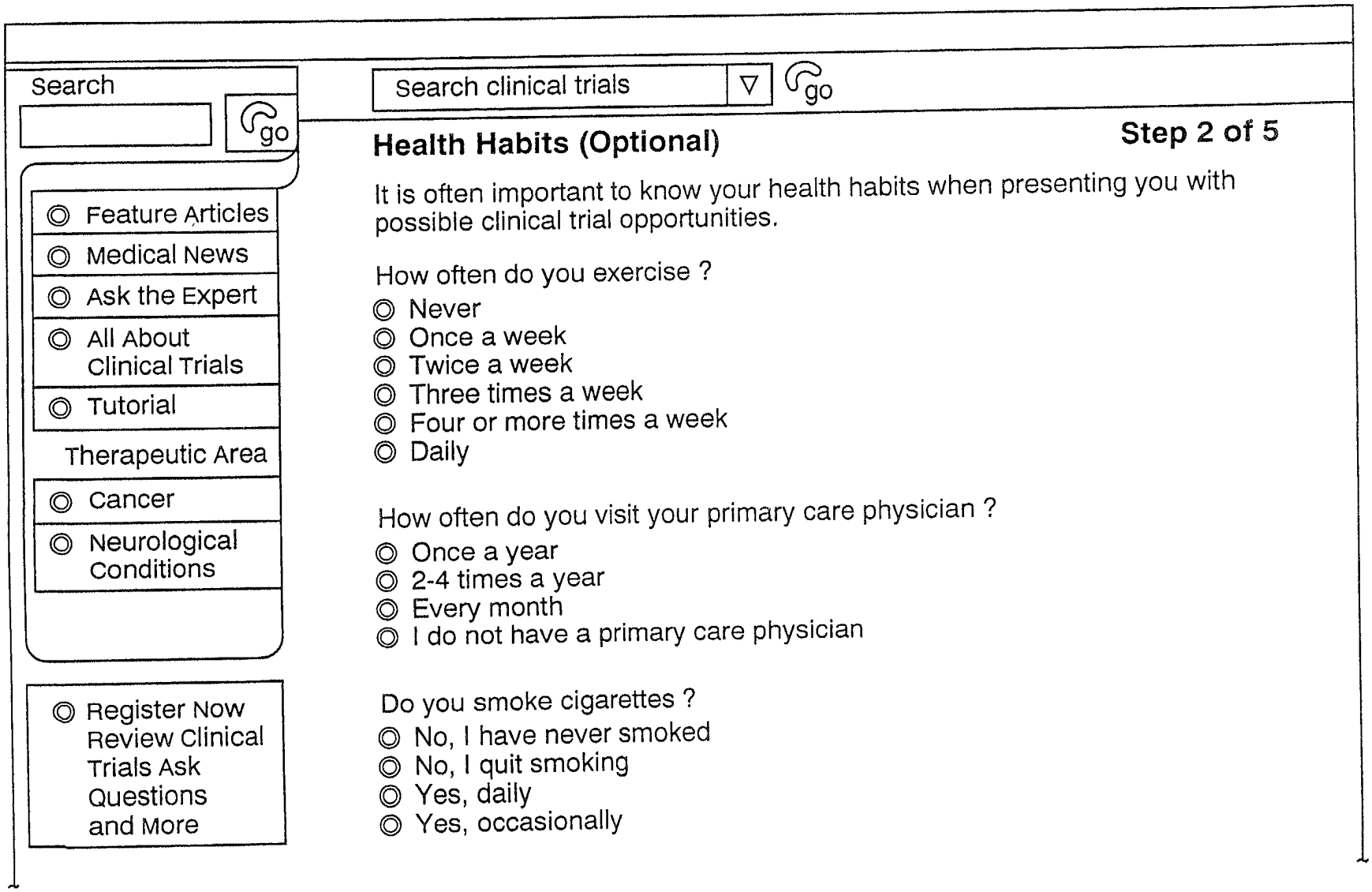
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Search clinical trials
go
Medications (Optional)
Step 1 of 5
Are you taking prescription (Rx) or over-the-counter (OTC) medications for these conditions ?
Your Medical Conditions
Prescription
Over-the-Counter
No Medications
Alopecia (Hair Loss)
Cancer: Prostate
Seizures (Epilepsy)
Do you take medications for any of the following conditions:
Medication
Yes
No
Allergies or Asthma
Heartburn
Diabetes
High Blood Pressure
Pain
Thyroid Disorders
Heart Conditions
Save and Continue
Save and Return to Previous Activity

FIG. 6J


Search
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Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Search clinical trials
go
Health Habits (Optional)
Step 2 of 5
It is often important to know your health habits when presenting you with possible clinical trial opportunities.
How often do you exercise ?
Never
Once a week
Twice a week
Three times a week
Four or more times a week
Daily
How often do you visit your primary care physician ?
Once a year
2-4 times a year
Every month
I do not have a primary care physician
Do you smoke cigarettes ?
No, I have never smoked
No, I quit smoking
Yes, daily
Yes, occasionally

FIG. 6K

If you smoke, how many cigarettes do you smoke per day ?
Please enter: [ ] Cigarettes Per Day

If you smoke, how old were you when you started smoking ?
Please enter: [ ] years old

Do you drink alcoholic beverages ?

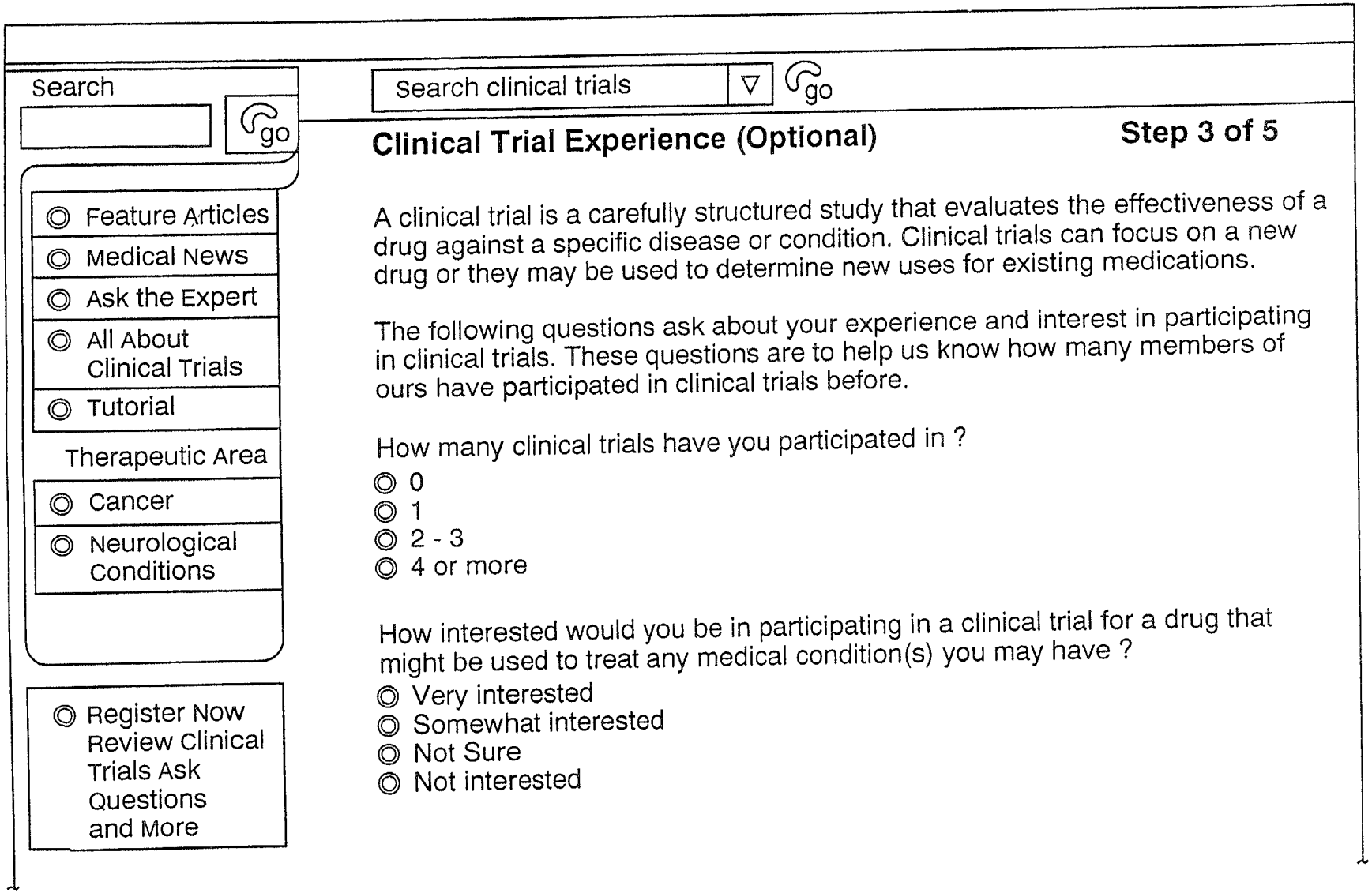
- ◎ No
- ◎ Yes, occasionally
- ◎ Yes, 1-2 drinks per day
- ◎ Yes, more than 2 drinks per day

Overall, how would you rate your health ?

- ◎ Excellent
- ◎ Good
- ◎ Fair
- ◎ Poor

[Save and Continue]
[Save and Return to Previous Activity]

FIG. 6L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go
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Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Search clinical trials
go
Clinical Trial Experience (Optional)
Step 3 of 5
A clinical trial is a carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.
The following questions ask about your experience and interest in participating in clinical trials. These questions are to help us know how many members of ours have participated in clinical trials before.
How many clinical trials have you participated in ?
0
1
2 - 3
4 or more
How interested would you be in participating in a clinical trial for a drug that might be used to treat any medical condition(s) you may have ?
Very interested
Somewhat interested
Not Sure
Not interested

FIG. 6M

If interested in clinical trial participation how far would you be willing to travel to participate in a clinical trial ?

- ◎ 1 - 10 miles
- ◎ 11 - 50 miles
- ◎ 51 - 100 miles
- ◎ More than 100 miles
- ◎ Any distance

Save and Continue

Save and Return to Previous Activity

FIG. 6N

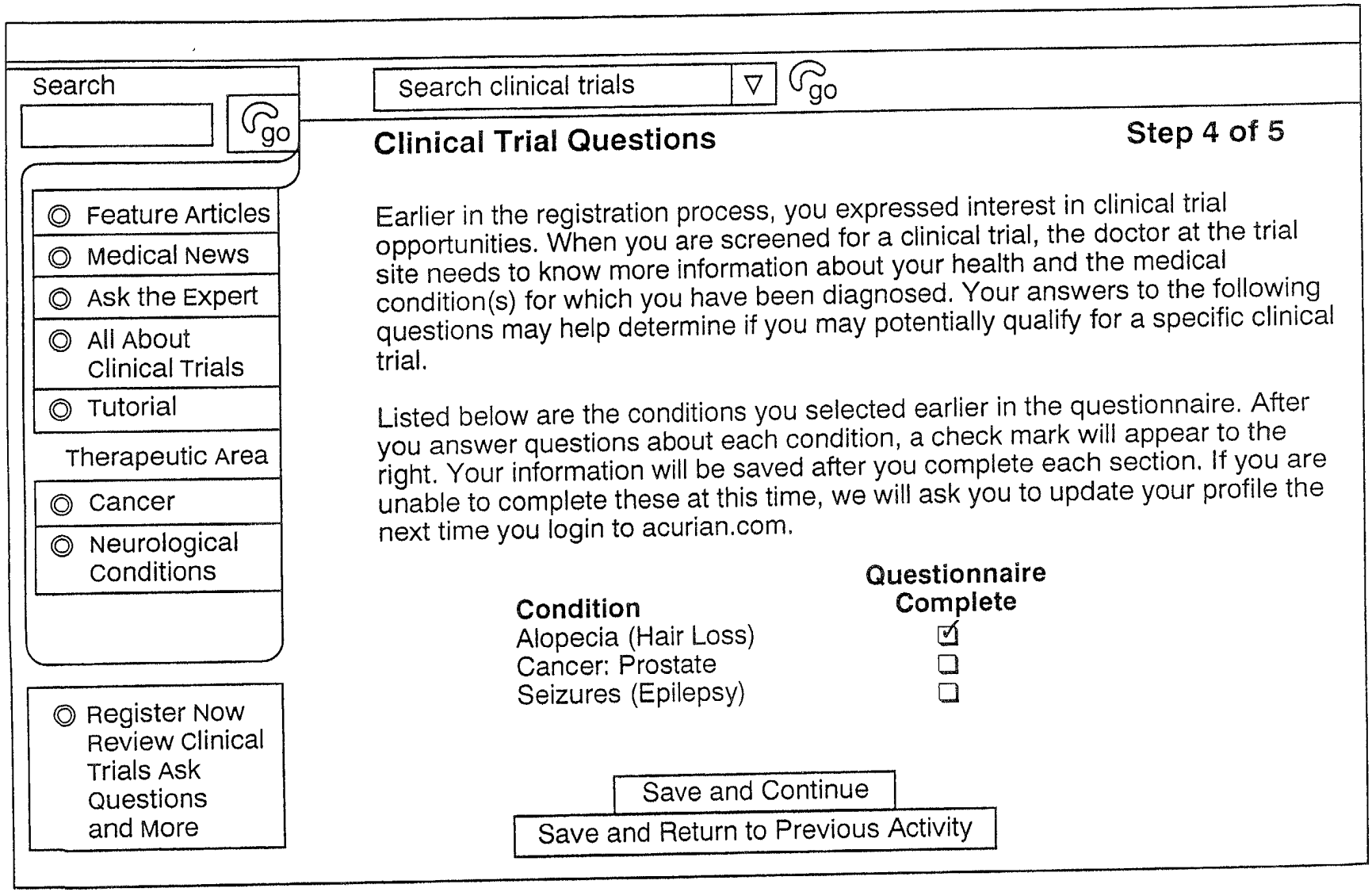

Search
go
Search clinical trials
go
Clinical Trial Questions
Step 4 of 5
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Earlier in the registration process, you expressed interest in clinical trial opportunities. When you are screened for a clinical trial, the doctor at the trial site needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.
Listed below are the conditions you selected earlier in the questionnaire. After you answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.
Condition
Questionnaire Complete
Alopecia (Hair Loss)
Cancer: Prostate
Seizures (Epilepsy)
Save and Continue
Save and Return to Previous Activity

FIG. 6O

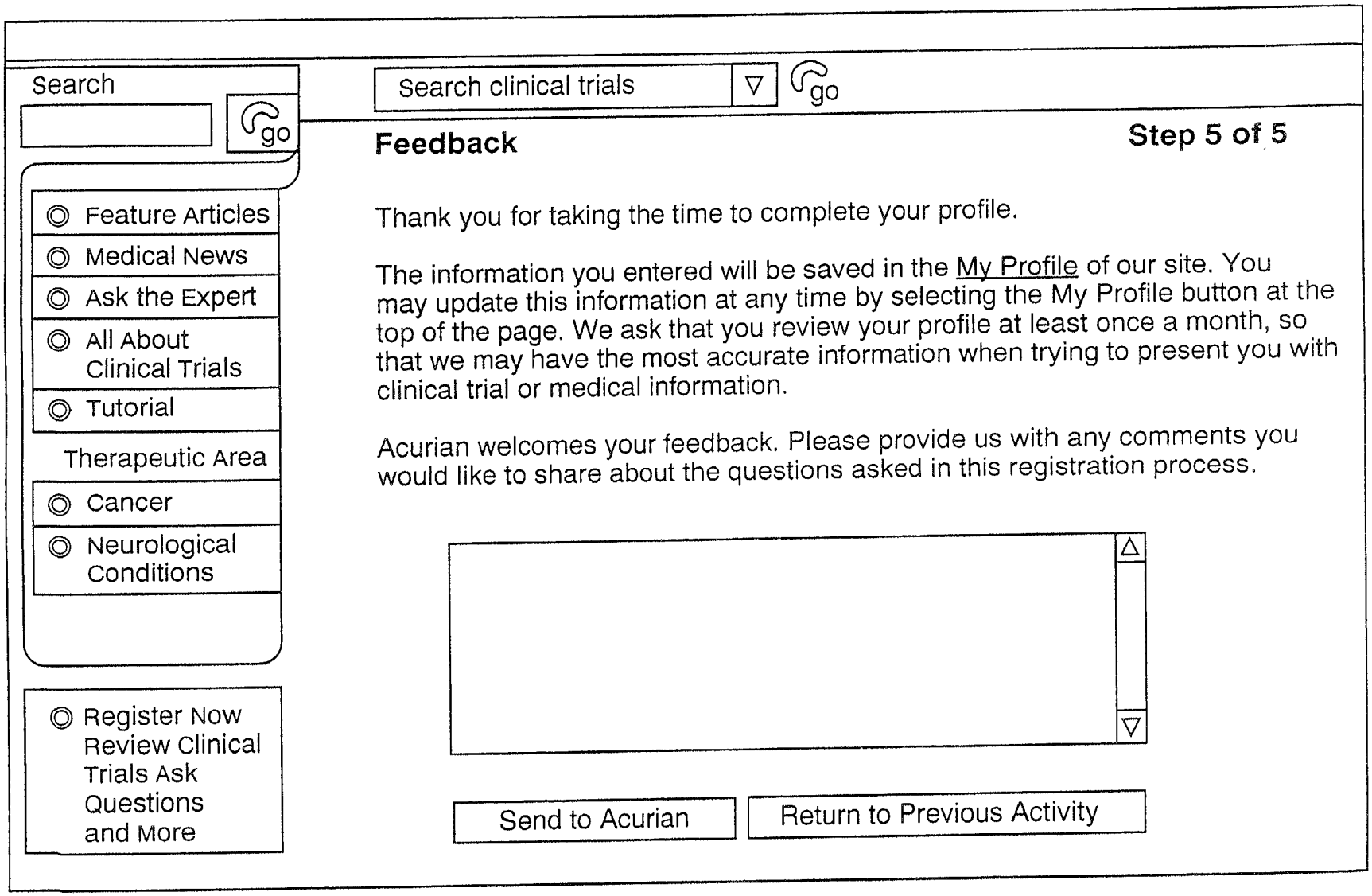

Search
go
Search clinical trials
go
Feedback
Step 5 of 5
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More
Thank you for taking the time to complete your profile.
The information you entered will be saved in the My Profile of our site. You may update this information at any time by selecting the My Profile button at the top of the page. We ask that you review your profile at least once a month, so that we may have the most accurate information when trying to present you with clinical trial or medical information.
Acurian welcomes your feedback. Please provide us with any comments you would like to share about the questions asked in this registration process.
Send to Acurian
Return to Previous Activity

FIG. 6P

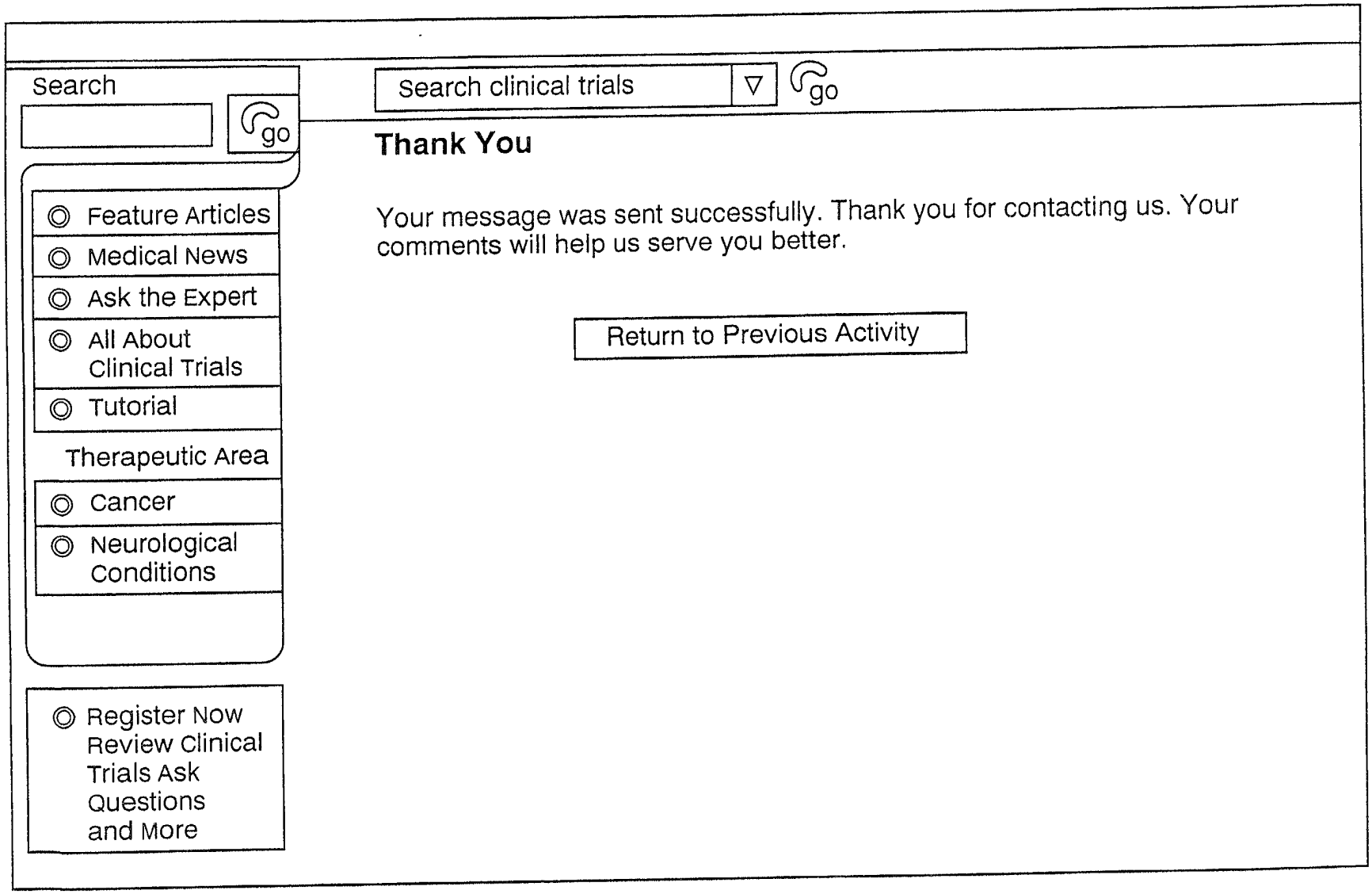
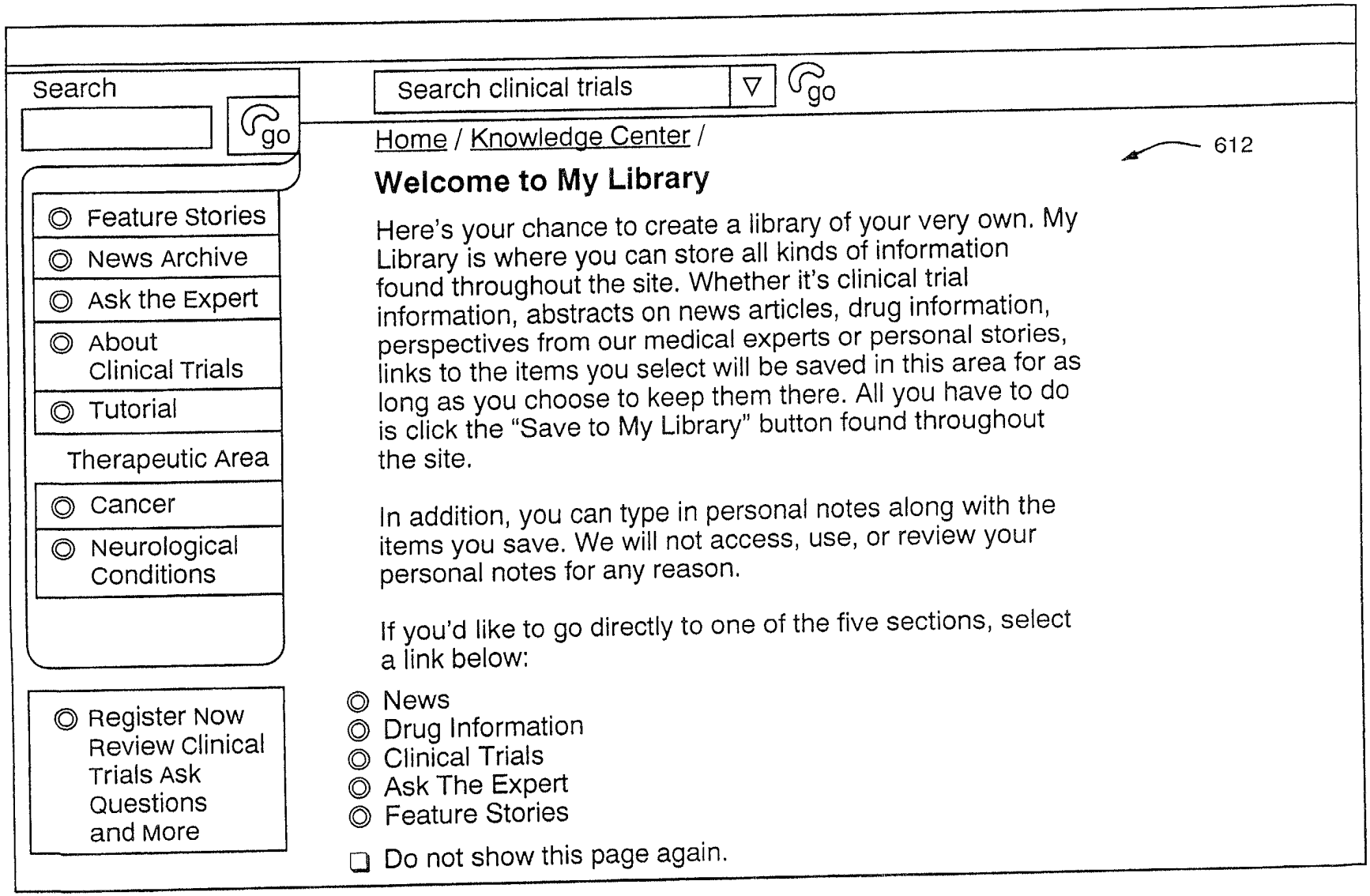

Search
go
Search clinical trials
go
Thank You
Your message was sent successfully. Thank you for contacting us. Your comments will help us serve you better.
Return to Previous Activity
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now Review Clinical Trials Ask Questions and More

FIG. 6Q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612
Welcome to My Library
Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information, perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.
In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.
If you'd like to go directly to one of the five sections, select a link below:
News
Drug Information
Clinical Trials
Ask The Expert
Feature Stories
Do not show this page again.

FIG. 6R

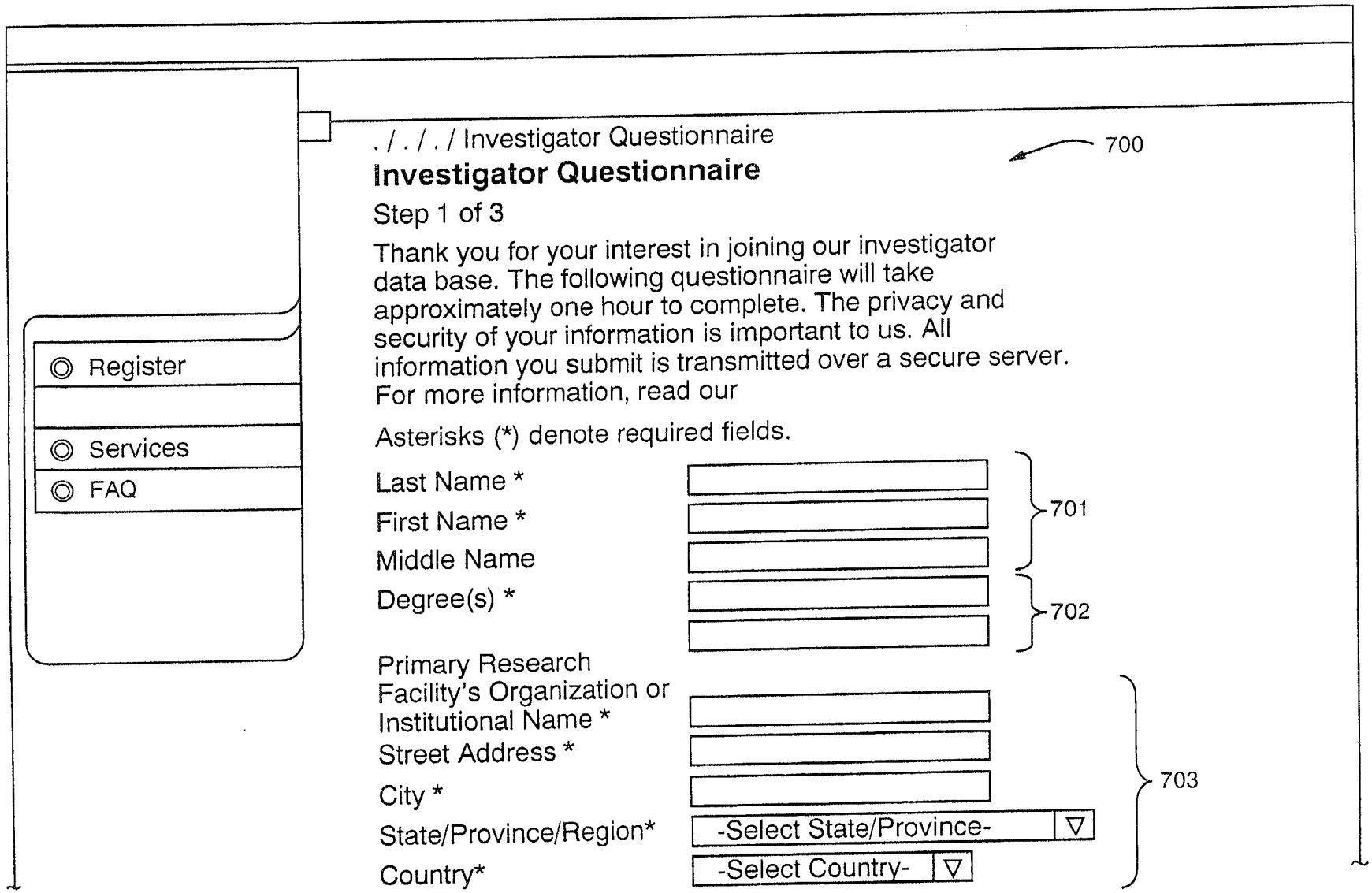

. / . / . / Investigator Questionnaire
700
Investigator Questionnaire
Step 1 of 3
Thank you for your interest in joining our investigator data base. The following questionnaire will take approximately one hour to complete. The privacy and security of your information is important to us. All information you submit is transmitted over a secure server. For more information, read our
Asterisks (*) denote required fields.
Register
Services
FAQ
Last Name *
First Name *
Middle Name
Degree(s) *
701
702
Primary Research Facility's Organization or Institutional Name *
Street Address *
City *
State/Province/Region*
-Select State/Province-
Country*
-Select Country-
703

FIG. 7A

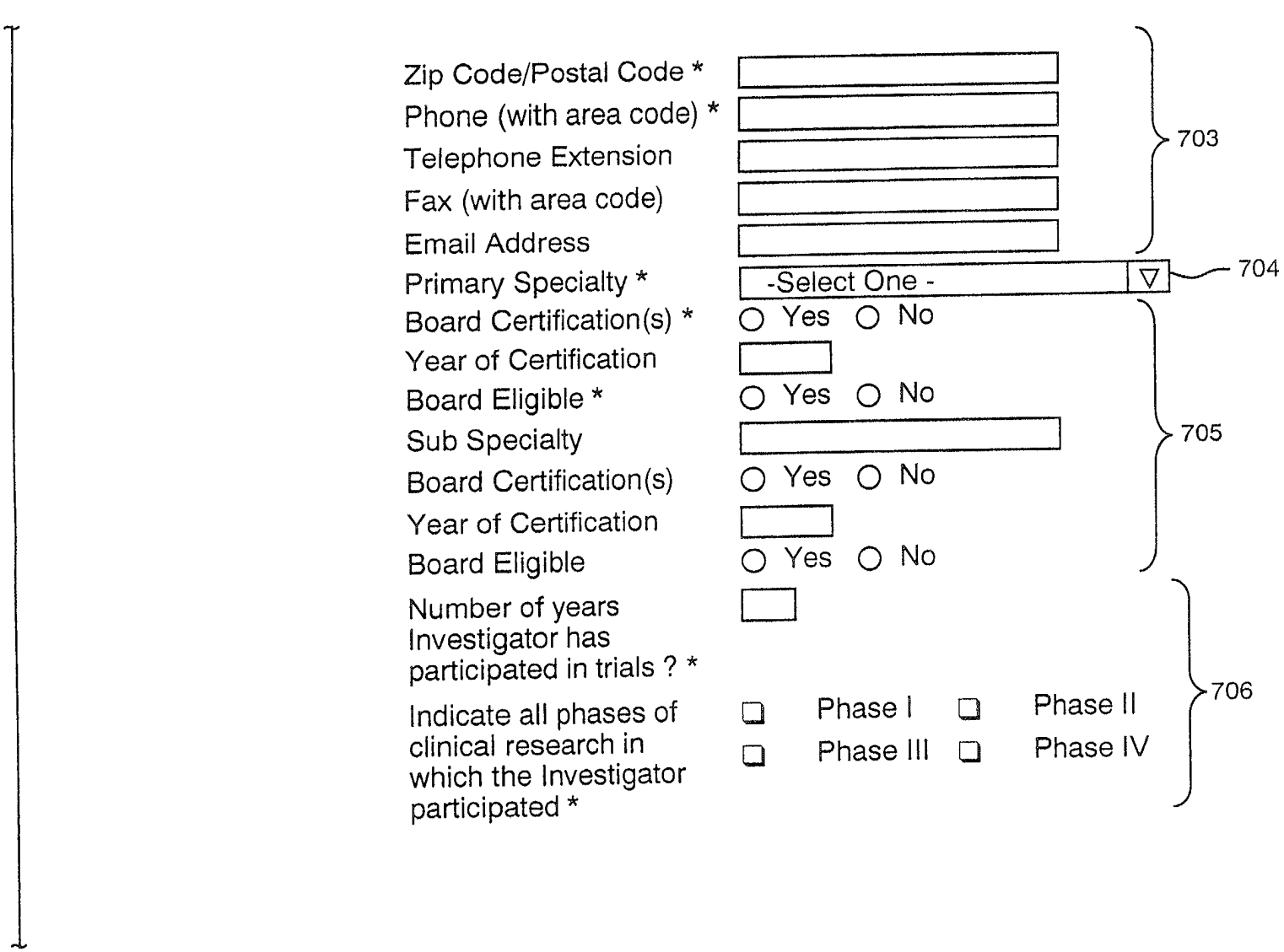

Zip Code/Postal Code *
Phone (with area code) *
Telephone Extension
Fax (with area code)
Email Address
703
Primary Specialty *
-Select One -
704
Board Certification(s) *
Yes
No
Year of Certification
Board Eligible *
Yes
No
Sub Specialty
705
Board Certification(s)
Yes
No
Year of Certification
Board Eligible
Yes
No
Number of years Investigator has participated in trials ? *
Indicate all phases of clinical research in which the Investigator participated *
Phase I
Phase II
Phase III
Phase IV
706

FIG. 7B

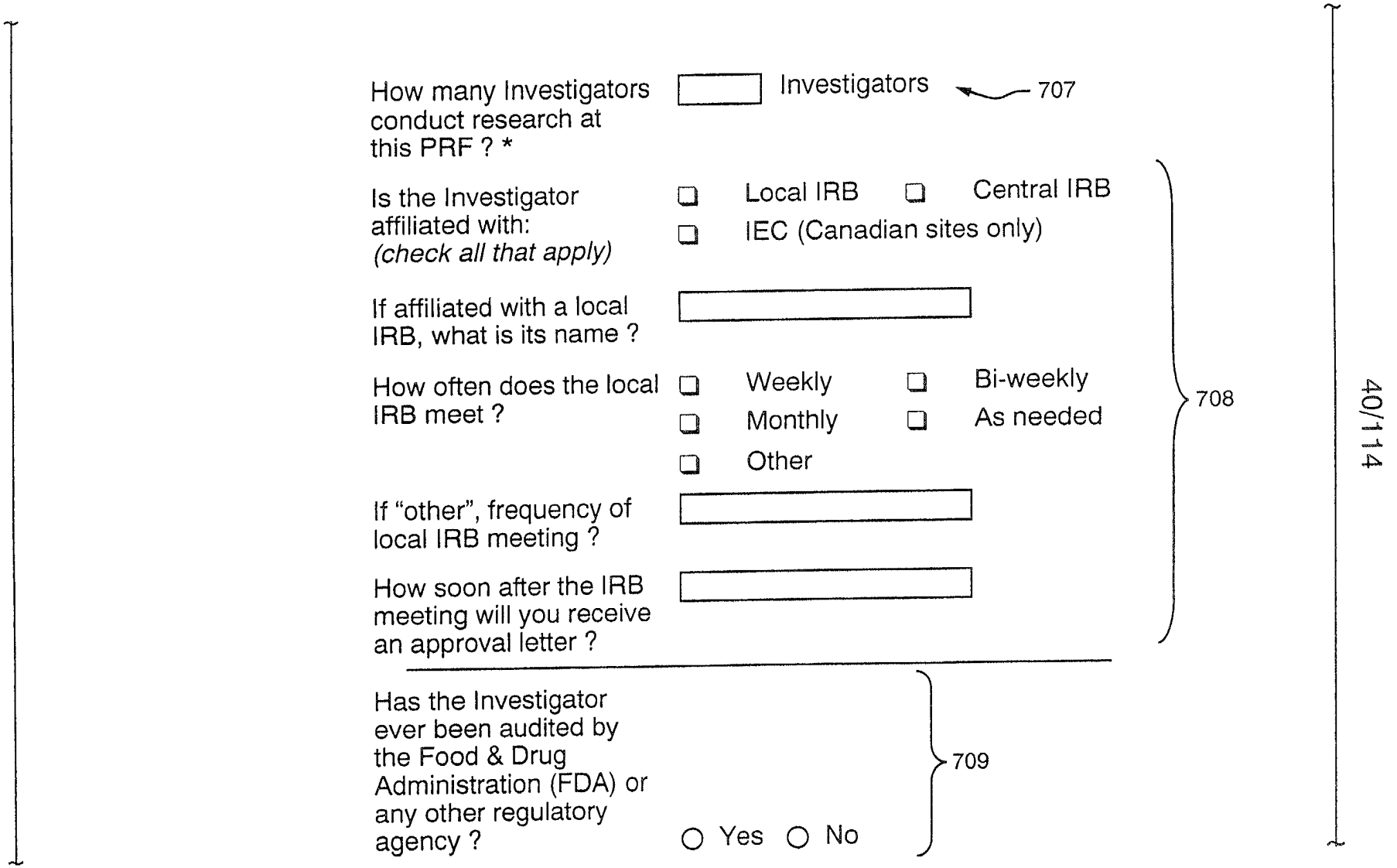

How many Investigators conduct research at this PRF ? *
Investigators
707
Is the Investigator affiliated with:
(check all that apply)
Local IRB
Central IRB
IEC (Canadian sites only)
If affiliated with a local IRB, what is its name ?
How often does the local IRB meet ?
Weekly
Bi-weekly
Monthly
As needed
Other
If "other", frequency of local IRB meeting ?
How soon after the IRB meeting will you receive an approval letter ?
708
Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency ?
Yes
No
709
40/114

FIG. 7C

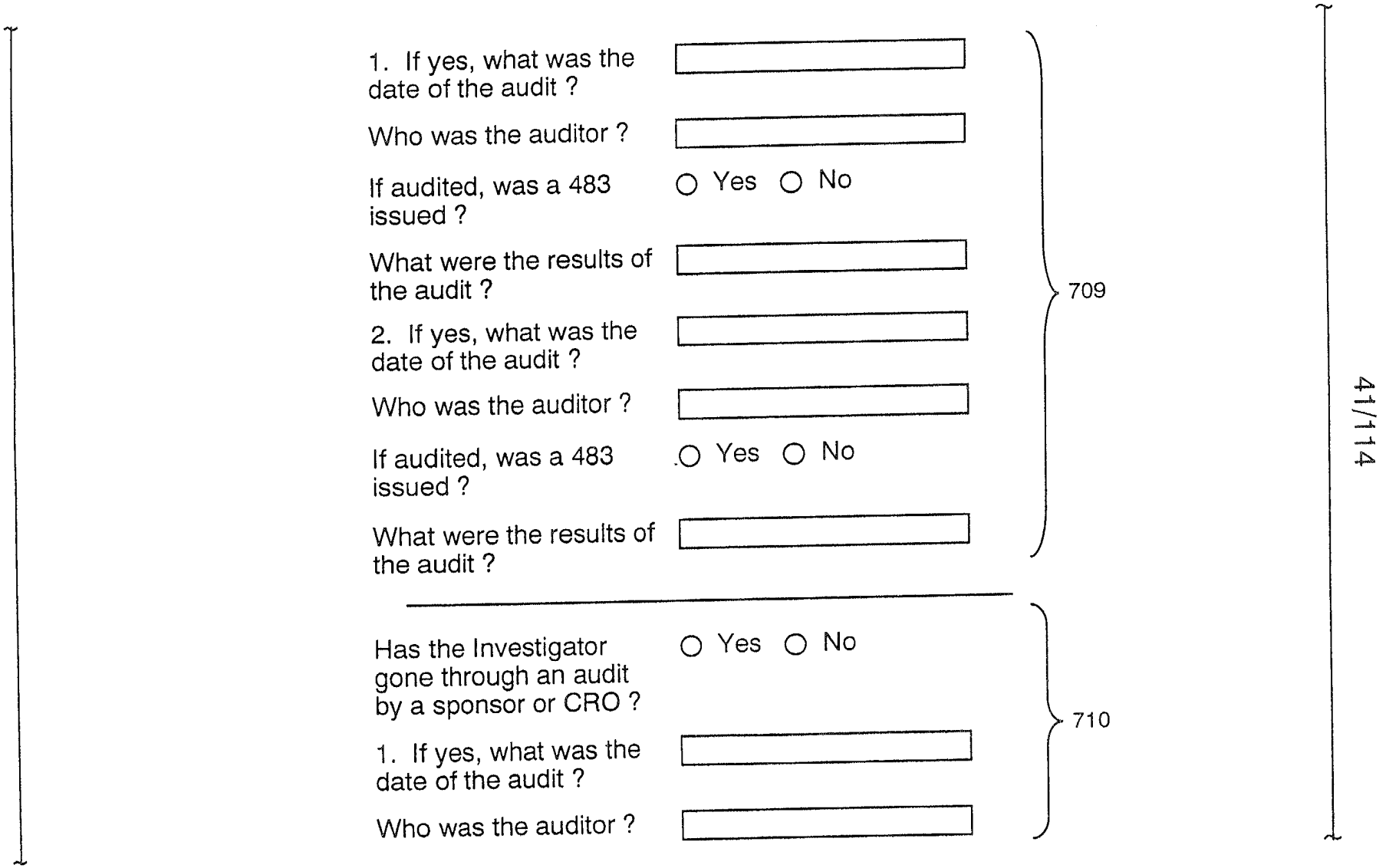

1. If yes, what was the date of the audit ?
Who was the auditor ?
If audited, was a 483 issued ?
O Yes O No
What were the results of the audit ?
2. If yes, what was the date of the audit ?
Who was the auditor ?
If audited, was a 483 issued ?
O Yes O No
What were the results of the audit ?
709
Has the Investigator gone through an audit by a sponsor or CRO ?
O Yes O No
1. If yes, what was the date of the audit ?
Who was the auditor ?
710
41/114

FIG. 7D

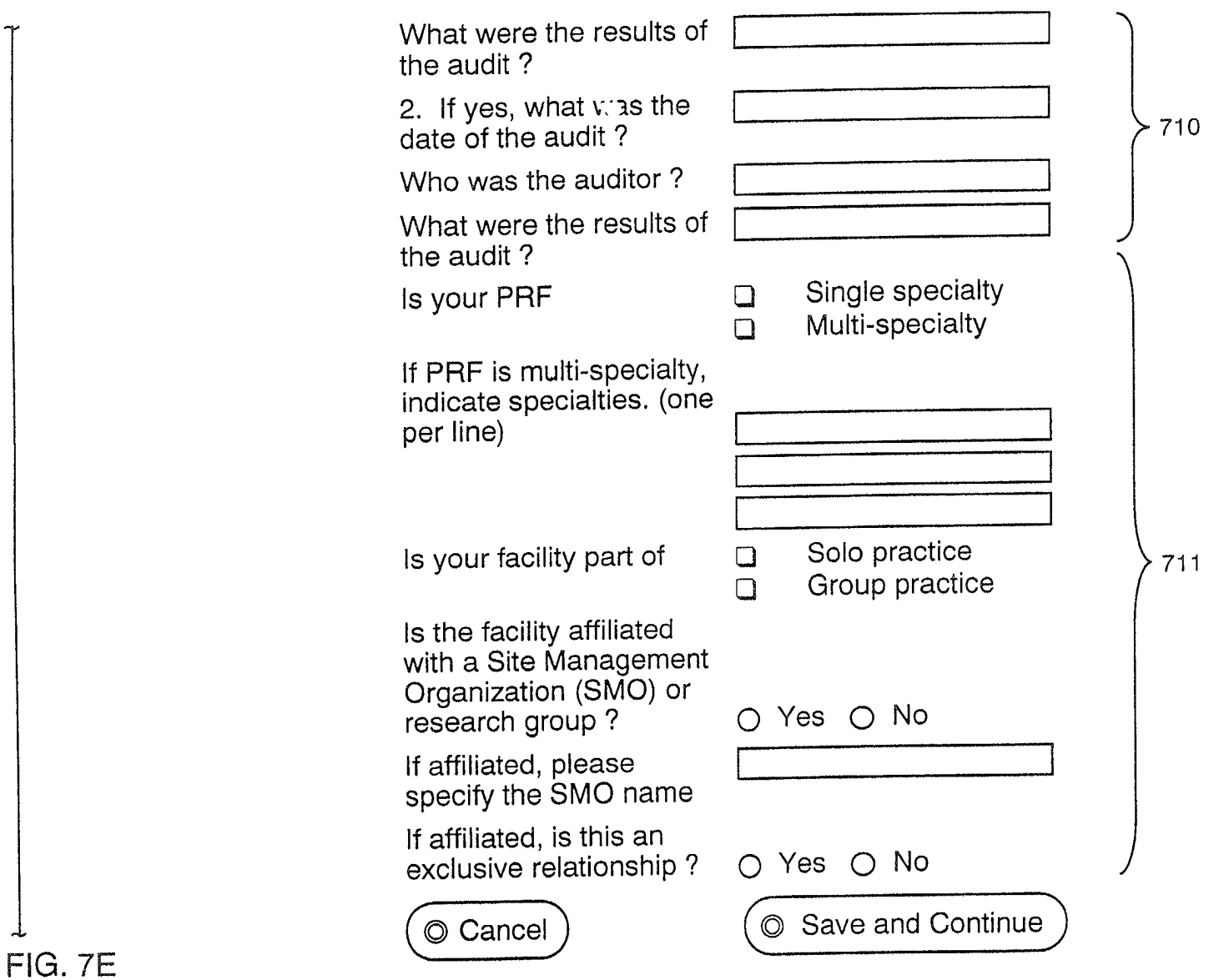

What were the results of the audit ?
2. If yes, what was the date of the audit ?
Who was the auditor ?
What were the results of the audit ?
710
Is your PRF
Single specialty
Multi-specialty
If PRF is multi-specialty, indicate specialties. (one per line)
Is your facility part of
Solo practice
Group practice
711
Is the facility affiliated with a Site Management Organization (SMO) or research group ?
Yes
No
If affiliated, please specify the SMO name
If affiliated, is this an exclusive relationship ?
Yes
No
Cancel
Save and Continue

FIG. 7E

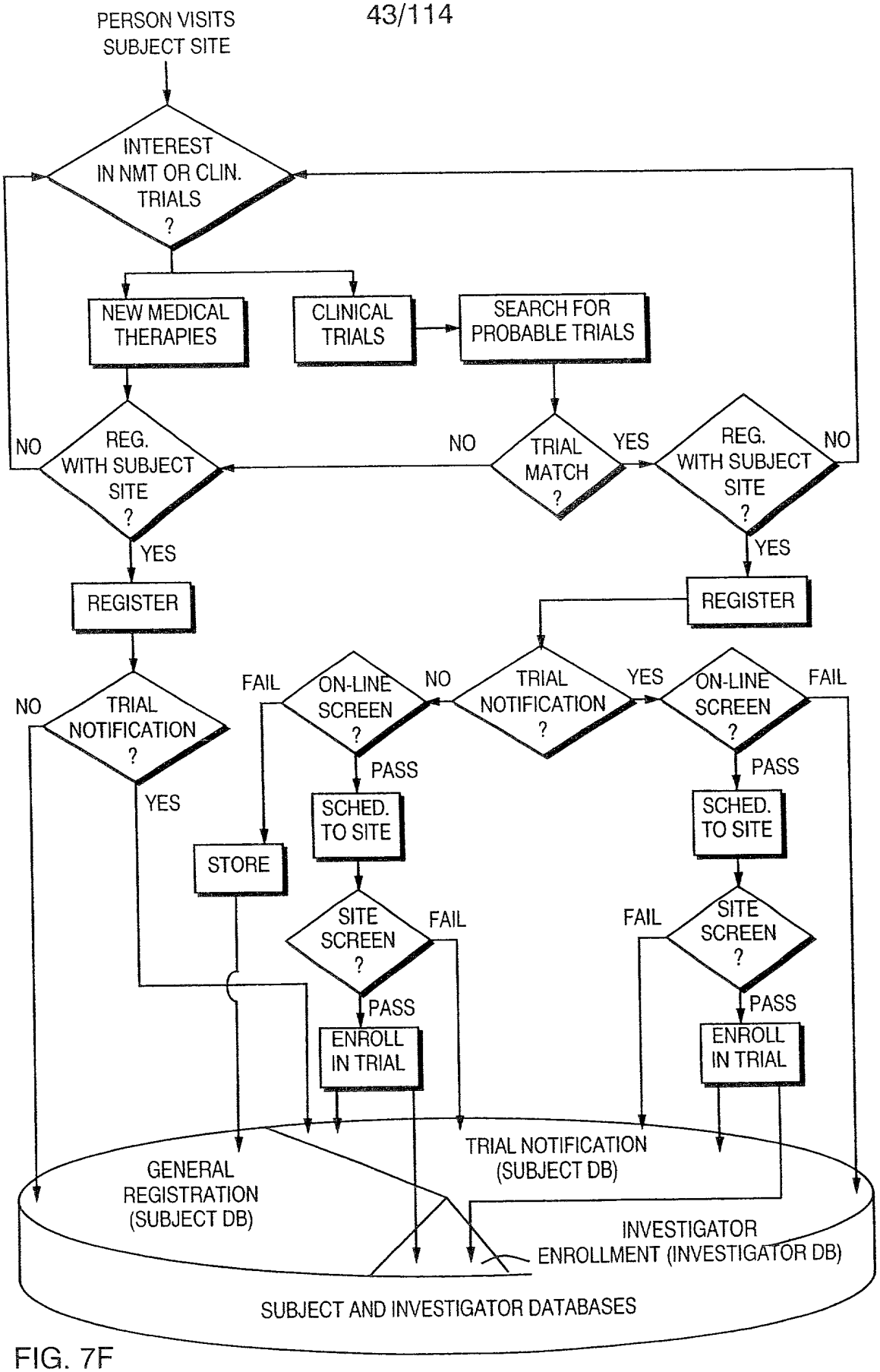

PERSON VISITS SUBJECT SITE
INTEREST IN NMT OR CLIN. TRIALS ?
NEW MEDICAL THERAPIES
CLINICAL TRIALS
SEARCH FOR PROBABLE TRIALS
NO
REG. WITH SUBJECT SITE ?
YES
REGISTER
NO
TRIAL MATCH ?
YES
REG. WITH SUBJECT SITE ?
NO
YES
REGISTER
NO
TRIAL NOTIFICATION ?
YES
FAIL
ON-LINE SCREEN ?
NO
PASS
SCHED. TO SITE
STORE
SITE SCREEN ?
FAIL
PASS
ENROLL IN TRIAL
TRIAL NOTIFICATION ?
YES
FAIL
ON-LINE SCREEN ?
PASS
SCHED. TO SITE
FAIL
SITE SCREEN ?
PASS
ENROLL IN TRIAL
GENERAL REGISTRATION (SUBJECT DB)
TRIAL NOTIFICATION (SUBJECT DB)
INVESTIGATOR ENROLLMENT (INVESTIGATOR DB)
SUBJECT AND INVESTIGATOR DATABASES

FIG. 7F

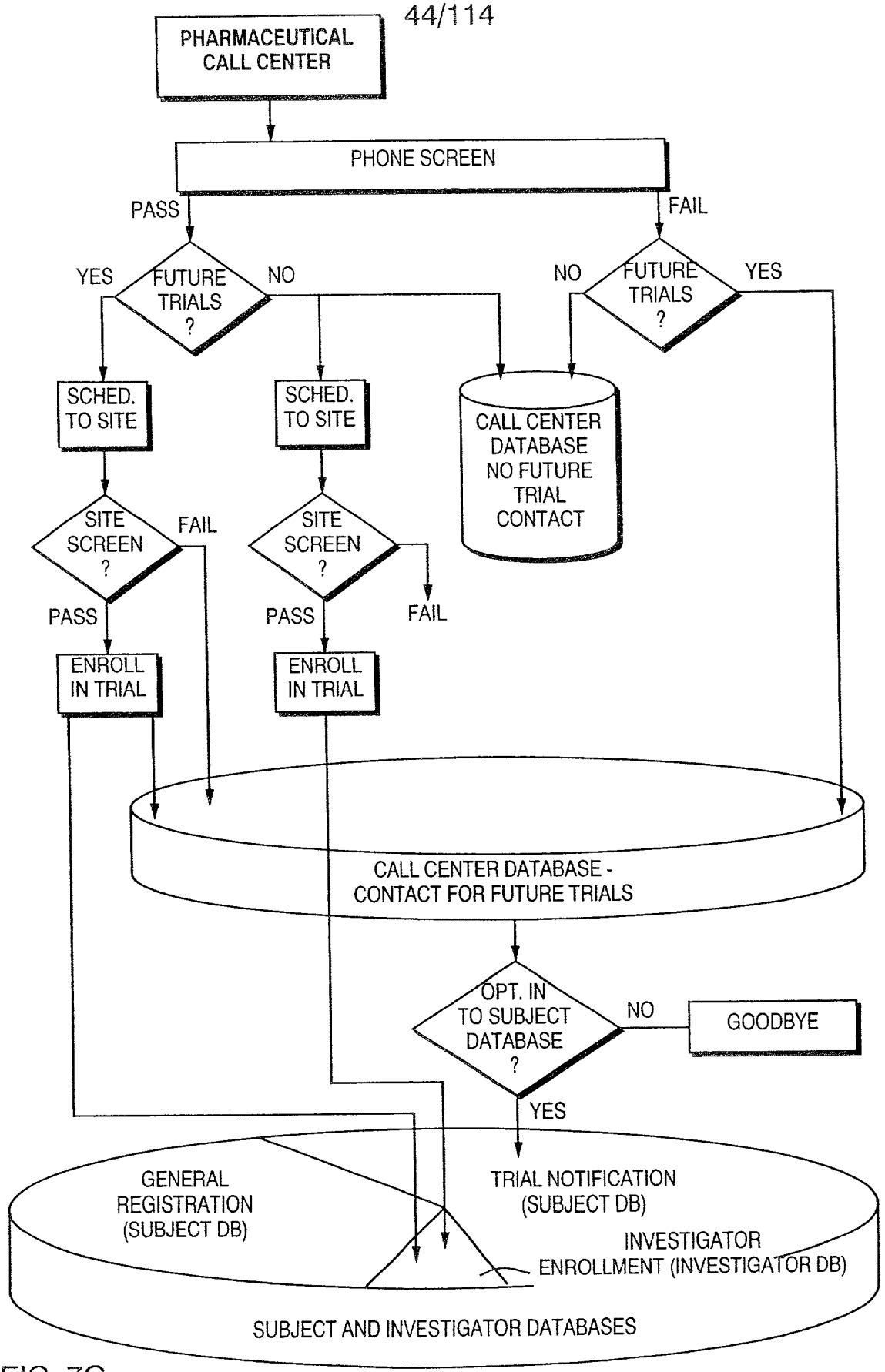

PHARMACEUTICAL CALL CENTER
PHONE SCREEN
PASS
FAIL
YES
FUTURE TRIALS ?
NO
NO
FUTURE TRIALS ?
YES
SCHED. TO SITE
SCHED. TO SITE
CALL CENTER DATABASE NO FUTURE TRIAL CONTACT
SITE SCREEN ?
FAIL
SITE SCREEN ?
PASS
FAIL
PASS
ENROLL IN TRIAL
ENROLL IN TRIAL
CALL CENTER DATABASE - CONTACT FOR FUTURE TRIALS
OPT. IN TO SUBJECT DATABASE ?
NO
GOODBYE
YES
GENERAL REGISTRATION (SUBJECT DB)
TRIAL NOTIFICATION (SUBJECT DB)
INVESTIGATOR ENROLLMENT (INVESTIGATOR DB)
SUBJECT AND INVESTIGATOR DATABASES

FIG. 7G

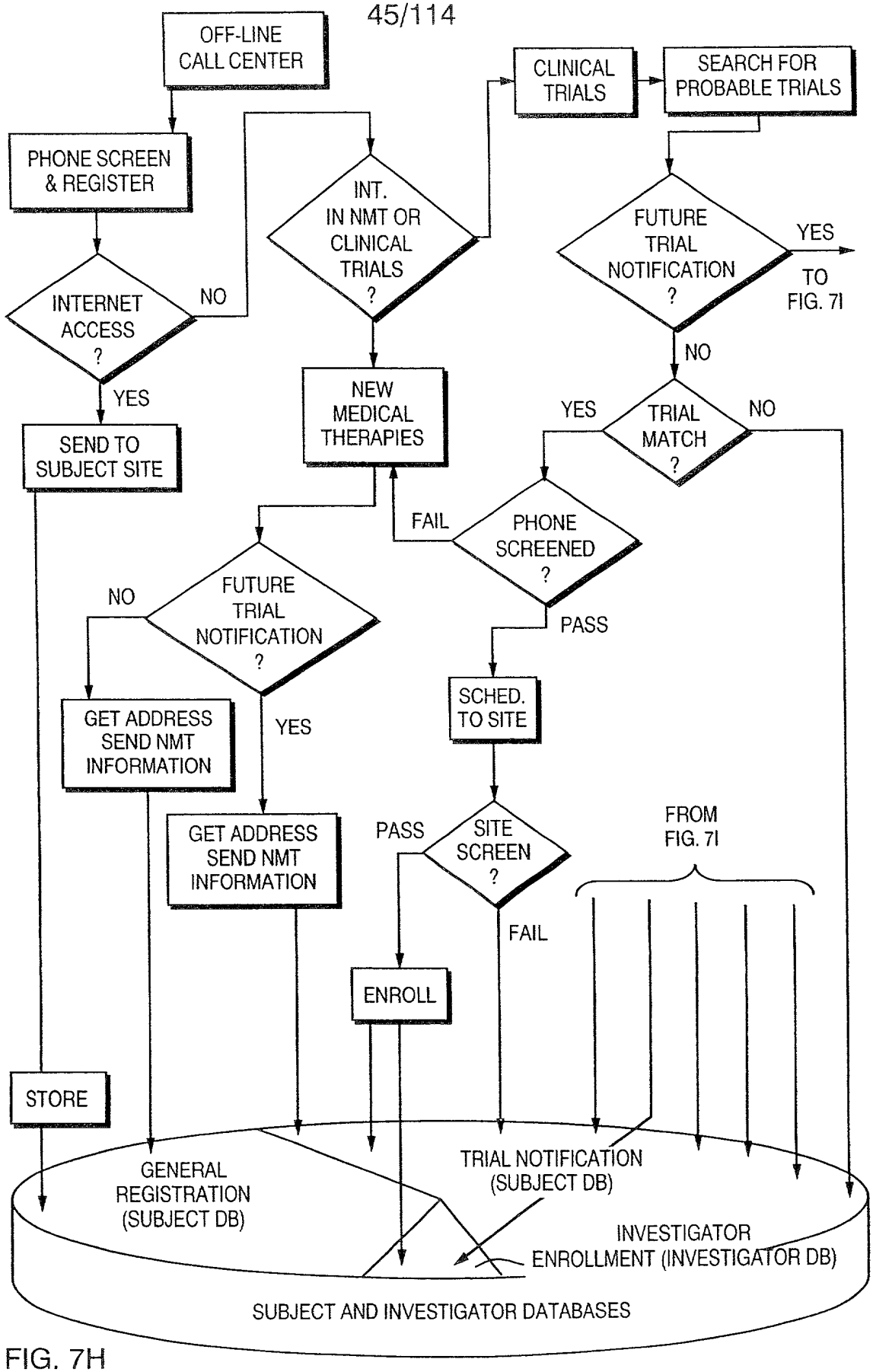

OFF-LINE CALL CENTER
PHONE SCREEN & REGISTER
INTERNET ACCESS ?
NO
YES
SEND TO SUBJECT SITE
INT. IN NMT OR CLINICAL TRIALS ?
NEW MEDICAL THERAPIES
CLINICAL TRIALS
SEARCH FOR PROBABLE TRIALS
FUTURE TRIAL NOTIFICATION ?
YES
TO FIG. 7I
NO
YES
TRIAL MATCH ?
NO
FAIL
PHONE SCREENED ?
PASS
NO
FUTURE TRIAL NOTIFICATION ?
YES
GET ADDRESS SEND NMT INFORMATION
GET ADDRESS SEND NMT INFORMATION
SCHED. TO SITE
PASS
SITE SCREEN ?
FAIL
FROM FIG. 7I
ENROLL
STORE
GENERAL REGISTRATION (SUBJECT DB)
TRIAL NOTIFICATION (SUBJECT DB)
INVESTIGATOR ENROLLMENT (INVESTIGATOR DB)
SUBJECT AND INVESTIGATOR DATABASES

FIG. 7H

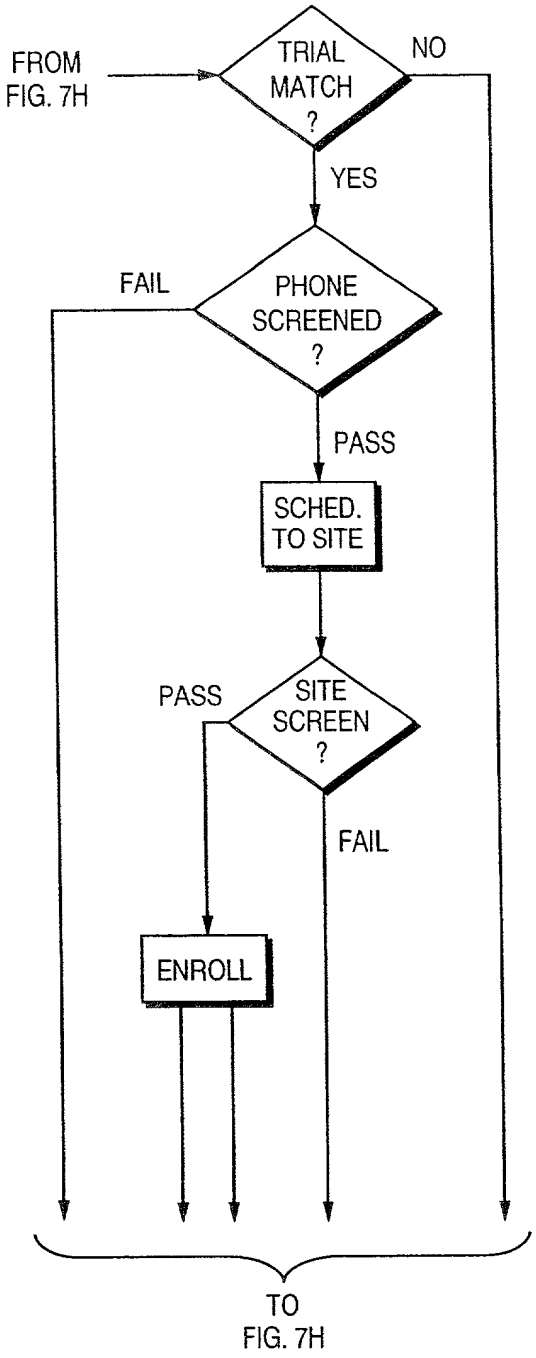

FROM
FIG. 7H
TRIAL
MATCH
?
NO
YES
FAIL
PHONE
SCREENED
?
PASS
SCHED.
TO SITE
PASS
SITE
SCREEN
?
FAIL
ENROLL
TO
FIG. 7H

FIG. 7I

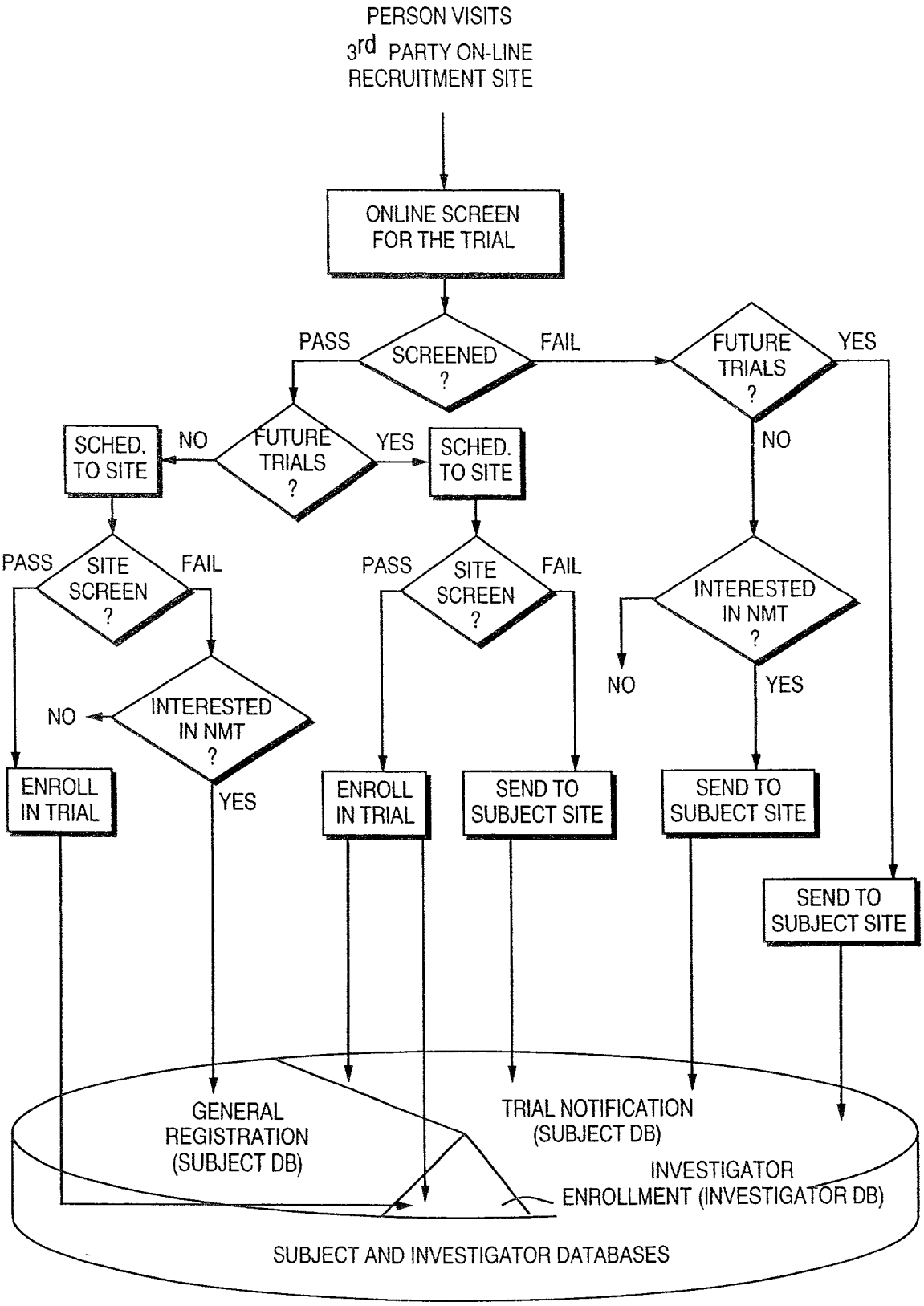

PERSON VISITS
3rd PARTY ON-LINE
RECRUITMENT SITE
ONLINE SCREEN
FOR THE TRIAL
SCREENED
?
PASS
FAIL
FUTURE
TRIALS
?
YES
NO
SCHED.
TO SITE
NO
FUTURE
TRIALS
?
YES
SCHED.
TO SITE
PASS
SITE
SCREEN
?
FAIL
PASS
SITE
SCREEN
?
FAIL
INTERESTED
IN NMT
?
NO
YES
NO
INTERESTED
IN NMT
?
ENROLL
IN TRIAL
YES
ENROLL
IN TRIAL
SEND TO
SUBJECT SITE
SEND TO
SUBJECT SITE
SEND TO
SUBJECT SITE
GENERAL
REGISTRATION
(SUBJECT DB)
TRIAL NOTIFICATION
(SUBJECT DB)
INVESTIGATOR
ENROLLMENT (INVESTIGATOR DB)
SUBJECT AND INVESTIGATOR DATABASES

FIG. 7J

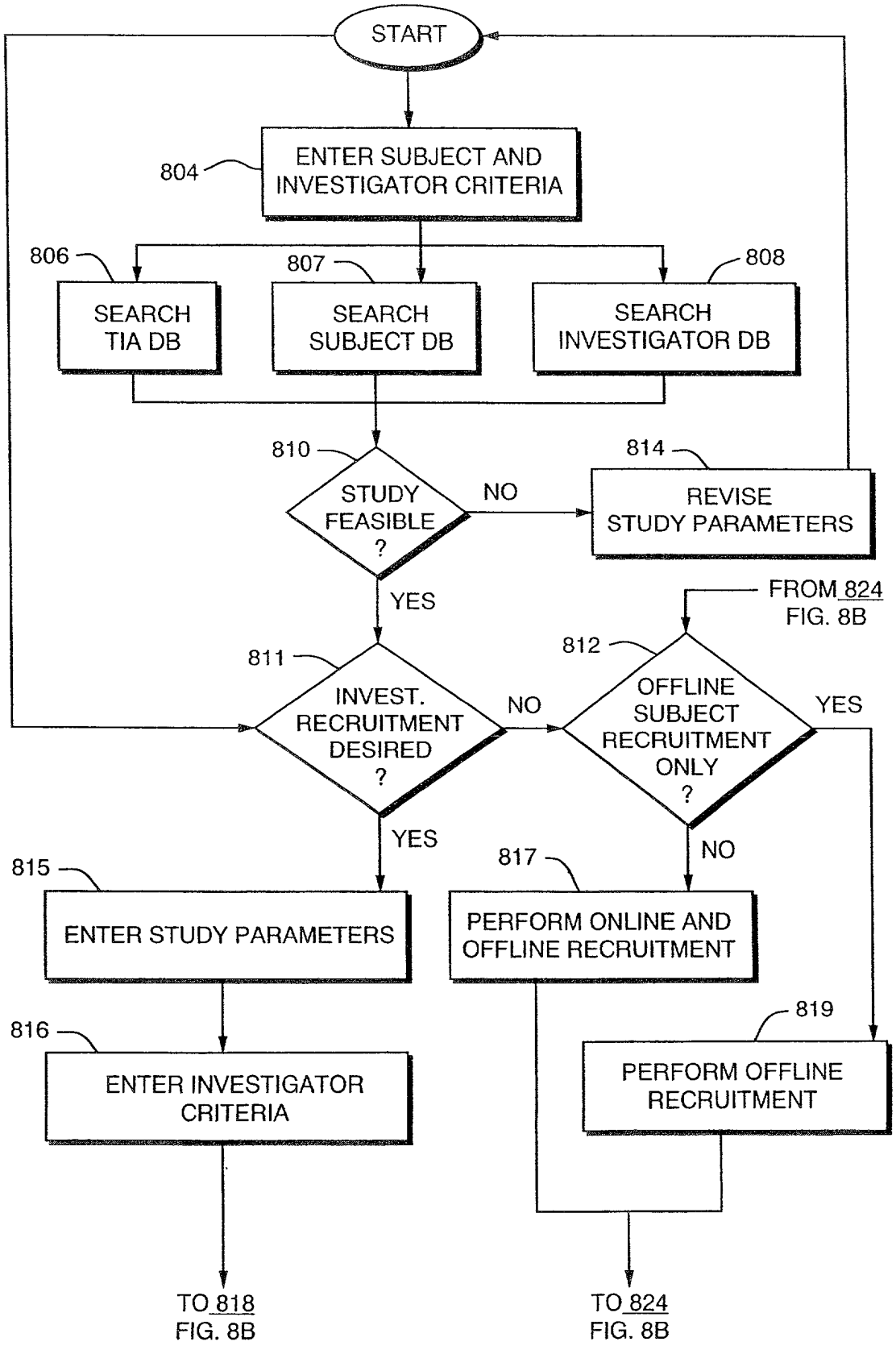

START
804
ENTER SUBJECT AND INVESTIGATOR CRITERIA
806
SEARCH TIA DB
807
SEARCH SUBJECT DB
808
SEARCH INVESTIGATOR DB
810
STUDY FEASIBLE ?
NO
814
REVISE STUDY PARAMETERS
YES
FROM 824 FIG. 8B
811
INVEST. RECRUITMENT DESIRED ?
NO
812
OFFLINE SUBJECT RECRUITMENT ONLY ?
YES
YES
NO
815
ENTER STUDY PARAMETERS
817
PERFORM ONLINE AND OFFLINE RECRUITMENT
816
ENTER INVESTIGATOR CRITERIA
819
PERFORM OFFLINE RECRUITMENT
TO 818 FIG. 8B
TO 824 FIG. 8B

FIG. 8A

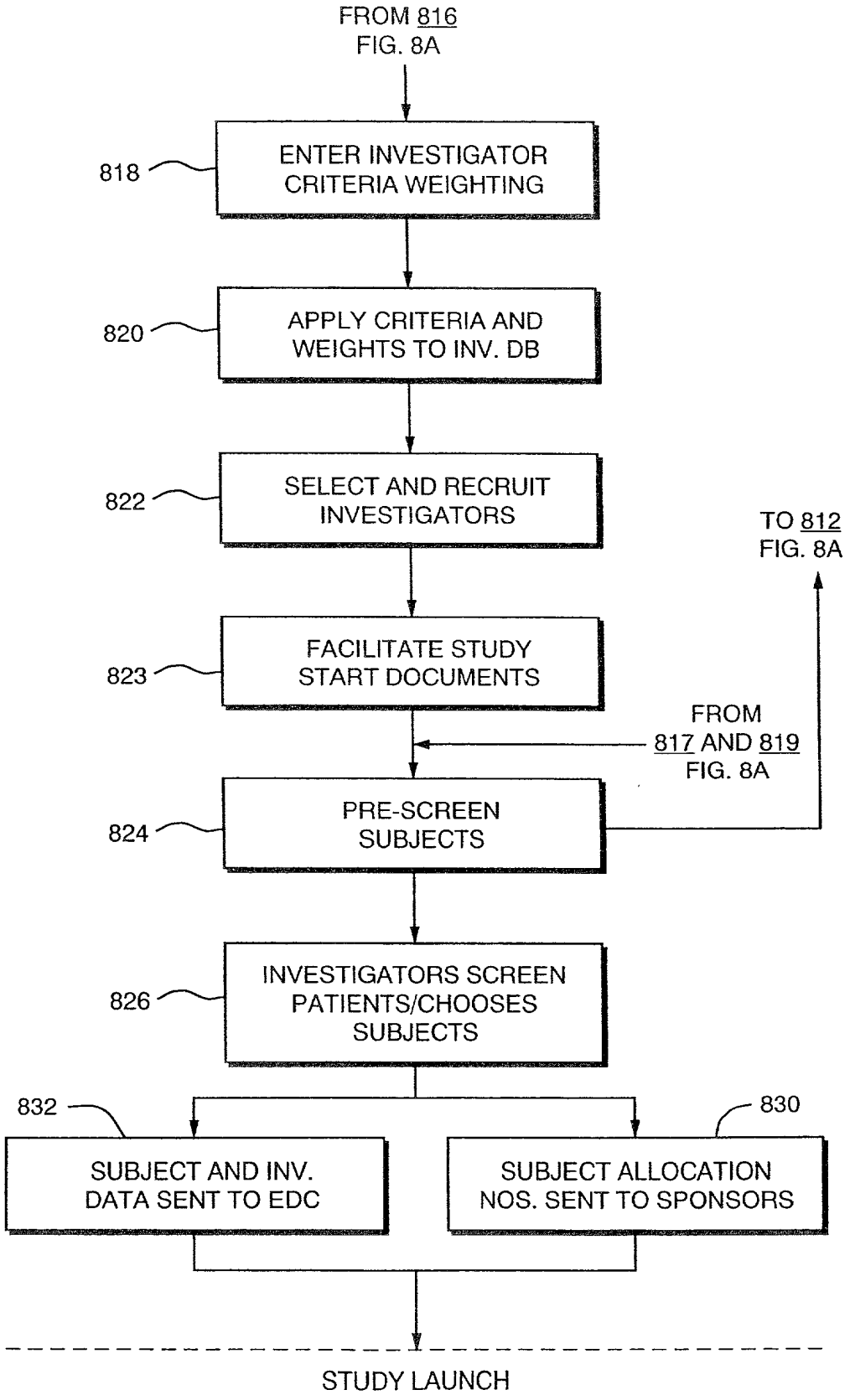

FROM 816
FIG. 8A
818
ENTER INVESTIGATOR CRITERIA WEIGHTING
820
APPLY CRITERIA AND WEIGHTS TO INV. DB
822
SELECT AND RECRUIT INVESTIGATORS
TO 812
FIG. 8A
823
FACILITATE STUDY START DOCUMENTS
FROM 817 AND 819
FIG. 8A
824
PRE-SCREEN SUBJECTS
826
INVESTIGATORS SCREEN PATIENTS/CHOOSES SUBJECTS
832
830
SUBJECT AND INV. DATA SENT TO EDC
SUBJECT ALLOCATION NOS. SENT TO SPONSORS
STUDY LAUNCH

FIG. 8B

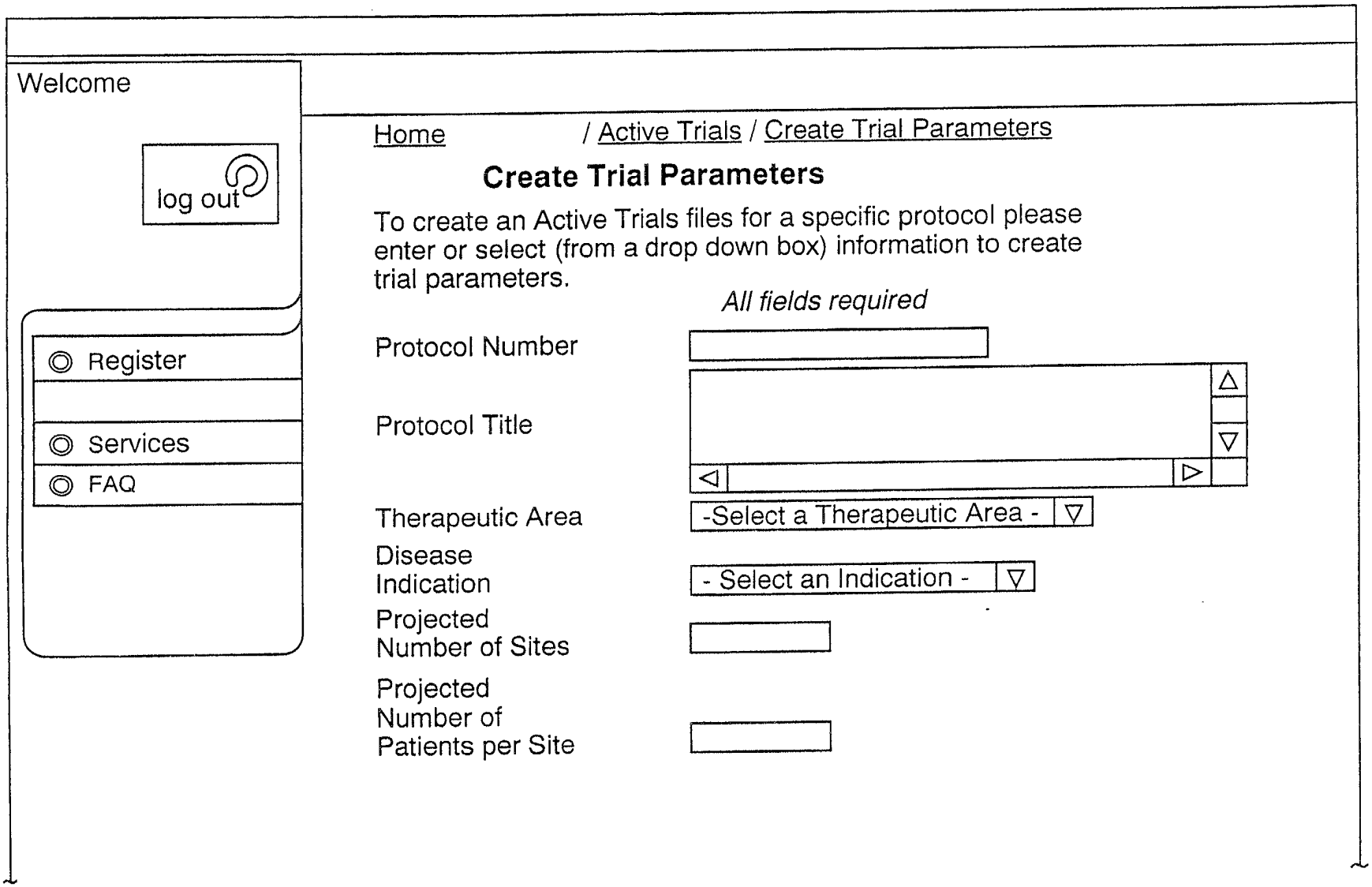

Welcome
log out
Register
Services
FAQ
Home / Active Trials / Create Trial Parameters
Create Trial Parameters
To create an Active Trials files for a specific protocol please enter or select (from a drop down box) information to create trial parameters.
All fields required
Protocol Number
Protocol Title
Therapeutic Area
-Select a Therapeutic Area -
Disease Indication
- Select an Indication -
Projected Number of Sites
Projected Number of Patients per Site
50/114

FIG. 9A

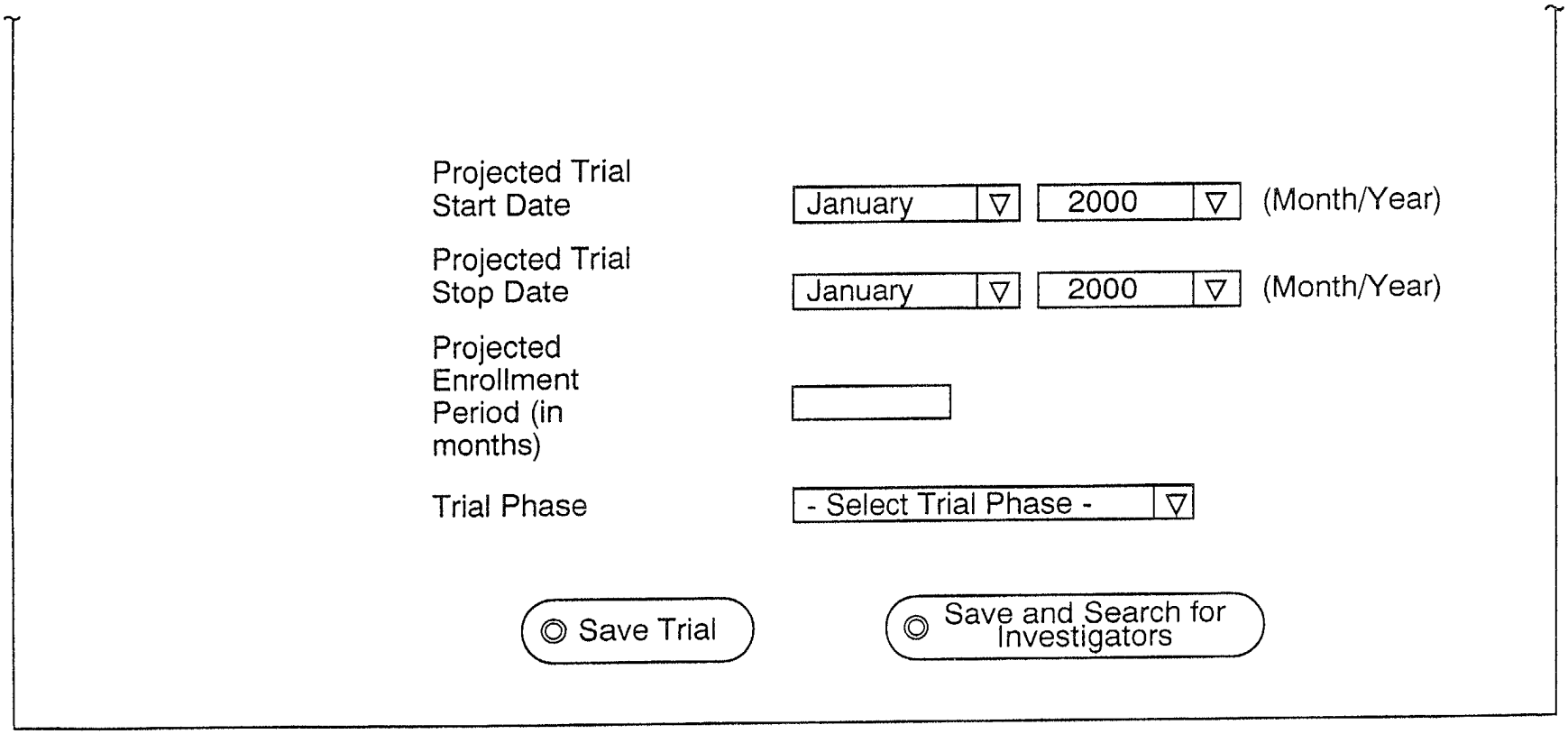
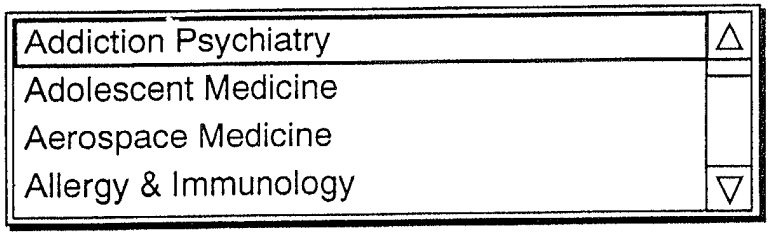

Projected Trial Start Date
January
2000
(Month/Year)
Projected Trial Stop Date
January
2000
(Month/Year)
Projected Enrollment Period (in months)
Trial Phase
- Select Trial Phase -
Save Trial
Save and Search for Investigators

FIG. 9B

Step 1:

To identify potential investigators - please select a specialty.

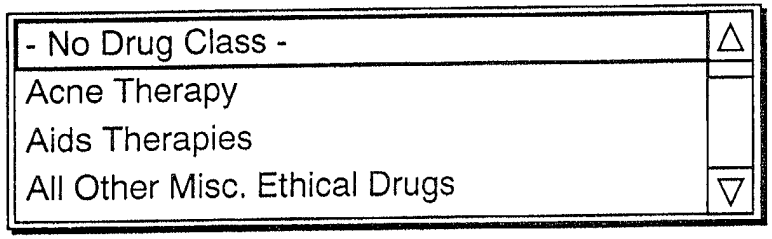
Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.



Step 2:

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication. (optional)

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.



Step 3:

To include the number of trials conducted by the investigator in the search, enter a number. (optional)

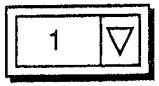


FIG. 10A

Step 4:

To access additional databases to enhance the investigator selection process, enter selections below. (optional)

Patient Therapeutic Area

Patient Disease Indication

Patient Disease Indication Encounter Category

Note: To select more than one patient disease encounter category, point to the specialty and press control click. Limit of 2 selections.

- Select a Category -
Case Load Estimates - Malignancy of heptobiliary system of pancreas
Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas

Patient Distance from Site (in miles)

<=3

Step 5:

To limit search by geographical location - please enter your selections below.

Municipal Area

- Select a Municipal Area -

FIG. 10B

Welcome

Protocol Number
1234-5678

- ◎ Register
- ◎ Services
- ◎ FAQ
- ◎ Security & Privacy Policy
- ◎ Active Trials
- ◎ Create Trial

Home / / Active Trials / Trial at a Glance / Search

Investigator Search Results

The following investigator search results reflect the investigator search criteria and the patient demographic data selected in the Investigator Search. Review selections by scrolling down this page or by clicking here: Investigator Search Criteria Summary. Click a column heading to sort by that column.

Displaying 1-20 out of 682 results

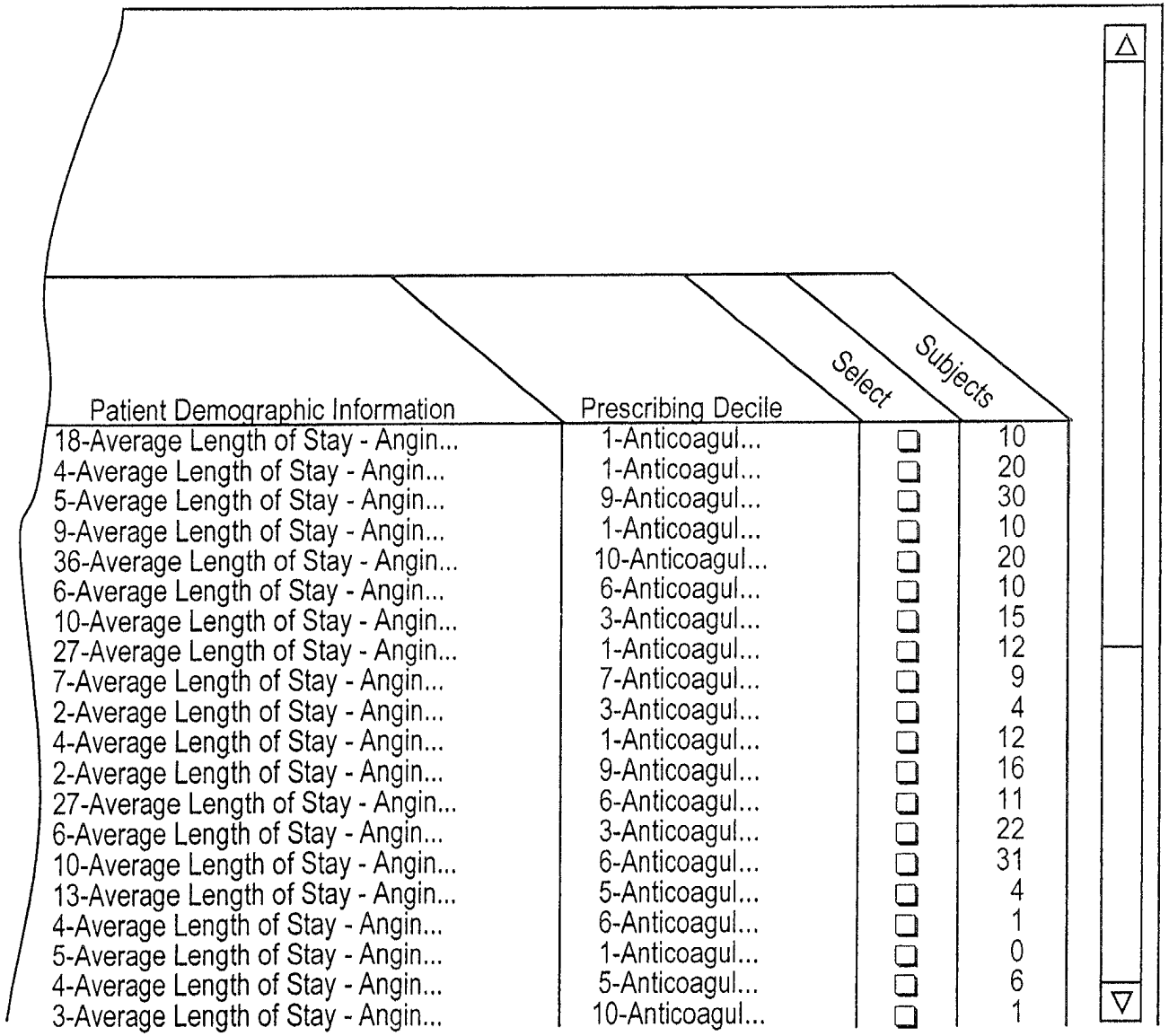
Search Results:

Name	Specialty	City, State	Total # of Trials
Jones, J	Cardiovascular Disease	SEATTLE, WA	33
Haspiel, J	Cardiovascular Disease	LA JOLLA, CA	28
Turco, C	Cardiovascular Disease	SALT LAKE CI, UT	27
Schelker, J	Cardiovascular Disease	MILWAUKEE, WI	27
Tucker, J	Cardiovascular Disease	CINCINNATI, OH	25
Robinson, C	Cardiovascular Disease	MCMURRAY, PA	25
Michelson, L	Cardiovascular Disease	OKLAHOMA CIT, OK	24
Kleger, B	Cardiovascular Disease	PITTSBURGH, PA	22
Doe, J	Cardiovascular Disease	SARASOTA, FL	20
Smith, S	Cardiovascular Disease	HILLSBORO, OR	19
Greene, M	Cardiovascular Disease	FOX POINT, WI	19
Watson, T	Cardiovascular Disease	FORT WAYNE, IN	17
Nicholas, J	Cardiovascular Disease	BALTIMORE, MD	16
Hamilton, P	Cardiovascular Disease	DURHAM, NC	16
Tang, H	Cardiovascular Disease	REDONDO BEAC, CA	15
Wilcox, J	Cardiovascular Disease	PEORIA, IL	13
Singer, j	Cardiovascular Disease	SANTA ROSA, CA	13
Restrepo, A	Cardiovascular Disease	CHARLESTON, SC	13
Grossman, D	Cardiovascular Disease	BUFFALO, NY	12
	Cardiovascular Disease	SELLERSVILLE, PA	12

Next 20 >

TO FIG. 11B

FIG. 11A



FROM FIG. 11A

FIG. 11B

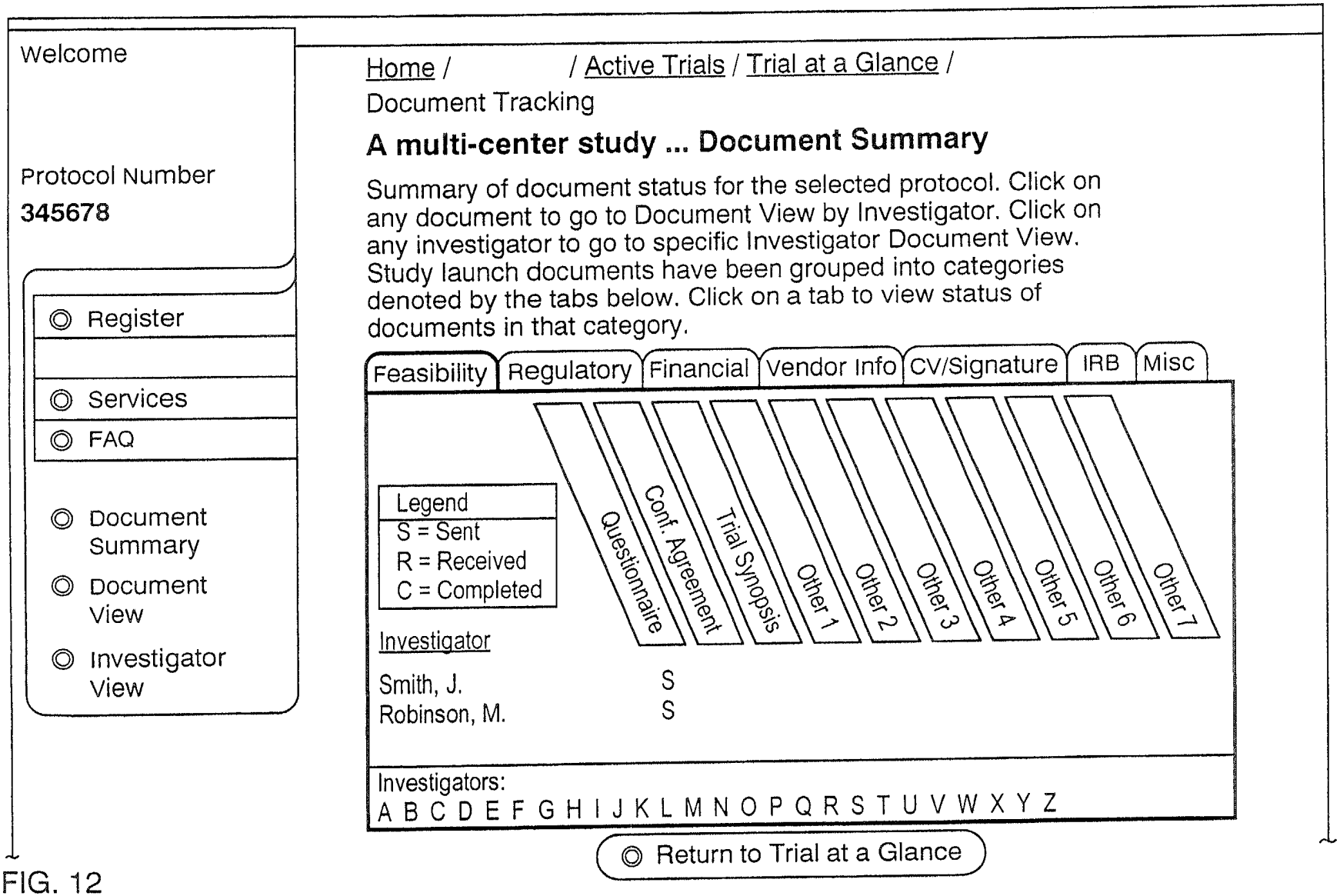

Welcome
Protocol Number
345678
Register
Services
FAQ
Document Summary
Document View
Investigator View
Home / / Active Trials / Trial at a Glance /
Document Tracking
A multi-center study ... Document Summary
Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.
Feasibility
Regulatory
Financial
Vendor Info
CV/Signature
IRB
Misc
Legend
S = Sent
R = Received
C = Completed
Questionnaire
Conf. Agreement
Trial Synopsis
Other 1
Other 2
Other 3
Other 4
Other 5
Other 6
Other 7
Investigator
Smith, J. S
Robinson, M. S
Investigators:
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
Return to Trial at a Glance

FIG. 12

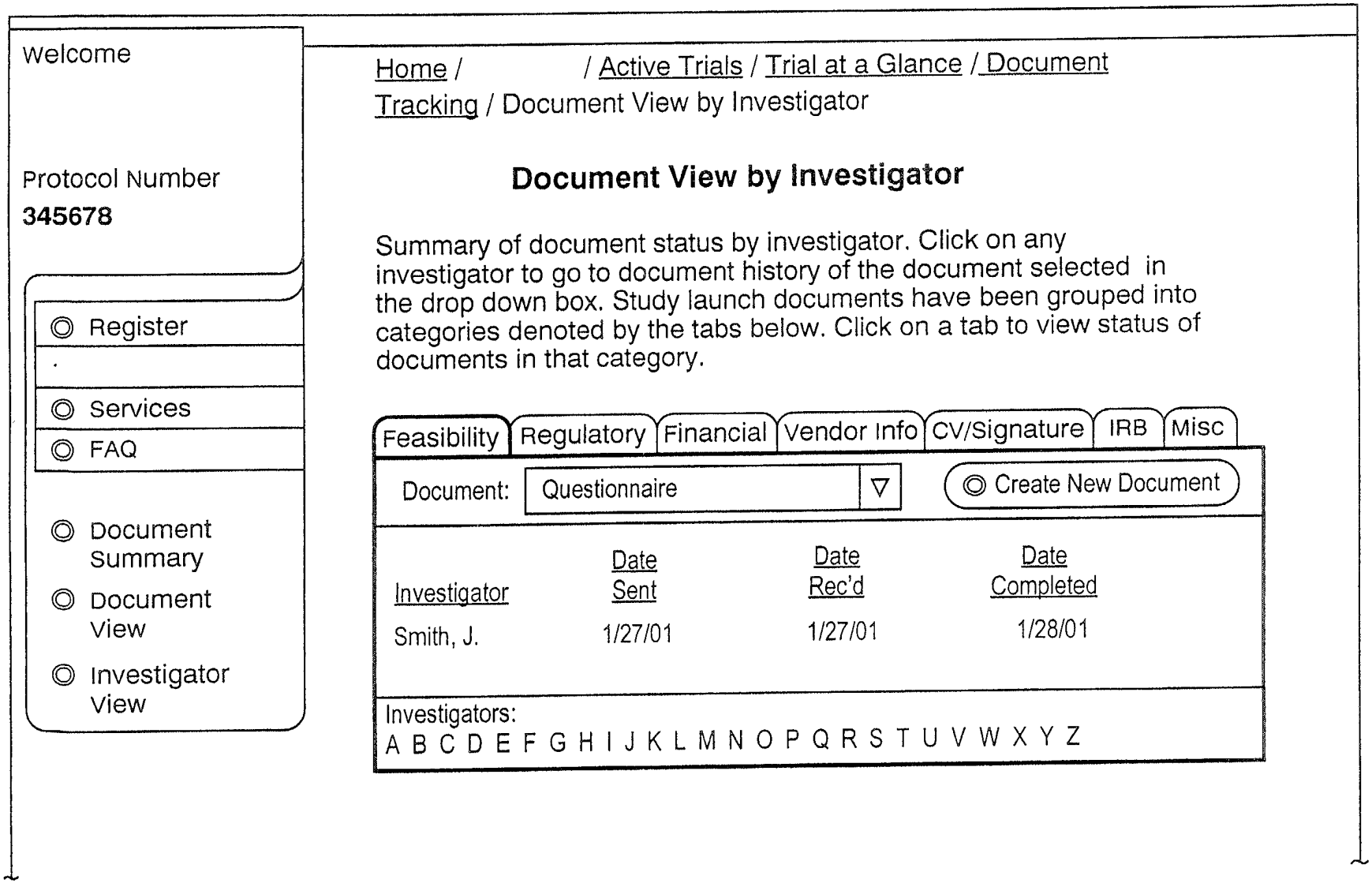

Welcome
Protocol Number
345678
Register
Services
FAQ
Document Summary
Document View
Investigator View
Home / / Active Trials / Trial at a Glance / Document Tracking / Document View by Investigator
Document View by Investigator
Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.
Feasibility
Regulatory
Financial
Vendor Info
CV/Signature
IRB
Misc
Document:
Questionnaire
Create New Document
Investigator
Date Sent
Date Rec'd
Date Completed
Smith, J.
1/27/01
1/27/01
1/28/01
Investigators:
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FIG. 13

From: Service Provider Sent: June 6, 2000
To: Ms. Moore
Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to http://www.website.com/study/zz-234567-22* and complete the study specific questionnaire.

Contact service.com with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.service.com/remove

FIG. 14

Questionnaire - Alzheimer's

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant ?
Yes, I am the potential study participant.
Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies.
No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.
- ○ Male
- ○ Female

How did you hear about this study ?
- ○ Internet
- ○ Newspaper Ad
- ○ Newspaper Article
- ○ Radio Ad
- ○ Radio Public Service Announcement
- ○ TV Ad
- ○ TV program
- ○ Physician
- ○ Friend
- ○ Support Group
- ○ Patient Ed Materials
- ○ Cardiology Newsletter
- ○ Other, please specify: _____

FIG. 15A

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease ?

- ○ Yes
- ○ No

Have you experienced a deterioration in memory over at least the last 6 months ?

- ○ Yes
- ○ No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- ○ orientation
- ○ judgement
- ○ problem solving
- ○ functioning in community affairs
- ○ functioning in home or hobbies
- ○ functioning in personal care

FIG. 15B

Do you live in a residential home ?
- ○ Yes
- ○ No

Click the box next to the person who will serve in the role of Caregiver:

I am the Caregiver
Friend
Relative
Paid personnel
No Caregiver

1. Please enter your date of birth:

Day Month Year (pull-down boxes)

- ☐ If female, continue with question 2
- ☐ If male, continue with question 6

2. Are you/Is (Patient) surgically sterile or post-menopausal for 1 year or more ?

- ○ Yes - continue with question #6
- ○ No - continue with question #3

3. Do you/Does (Patient) have any other neurological conditions such as:

- ○ Parkinson's disease
- ○ Pick's disease
- ○ Huntingtons chorea
- ○ Down's syndrome
- ○ Creutzfeldt-Jacob disease
- ○ Other _____

FIG. 15C

4. Do you now or did you at any time, have one or more of the following conditions resulting in your memory or *cognitive* impairment:

- ○ Major head injury
- ○ Injury caused by trauma such as boxing
- ○ Vitamin deficiency
  - ○ Type (drop down menu)
- ○ Brain abscess
- ○ Syphilis
- ○ Meningitis
- ○ AIDS
- ○ Brain cancer
- ○ Thyroid, parathyroid, or pituitary disease
- ○ Cushing's syndrome
- ○ Kidney failure
- ○ Uncontrolled diabetes
- ○ Mental retardation

5. Do you have a history of any of the following:

- ○ Stroke within the past 12 months
- ○ Epilepsy or convulsions (Childhood convulsions caused by fever continue)
- ○ Major depression
- ○ Stomach ulcer that is currently being treated
- ○ Liver, kidney, or lung disease
- ○ Kidney stones

6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months ?

- ○ No
- ○ Yes

FIG. 15D

7. Do you experience angina (chest pain) that required a change in medication in the past 3 months ?

- ○ Yes
- ○ No

8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute ?

- ○ Yes
- ○ No

9. Do you take medication for high blood pressure or chronic low blood pressure ?
- ○ Yes
  - ○ Medication(s) taken: (drop down menu)
- ○ No
- ○ Don't know

10. Do you take any medications for the purpose of treating memory loss such as dementia ?

- ○ Yes
- ○ No

11. Are you allergic to any medications ?

- ○ Yes
  - ○ Which Medication(s) (drop down menu)
- ○ No

FIG. 15E

12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba ?

- ○ Yes
  - ○ Which Medication(s) (drop down menu)
- ○ No

13. Have you ever been enrolled in a research study for galantamine ?

- ○ Yes
- ○ No
- ○ Don't know

14. Have you taken an investigational drug in the past 30 days or are you taking one now ?

- ○ No, I have not taken an investigational drug in the past 30 days
- ○ Yes, I have taken an investigational drug in the past 30 days
- ○ Yes, I am taking an investigational drug now

15. How many drinks do you consume in a typical 24-hour period ?

- ○ 1-2 drinks
- ○ 3-5 drinks
- ○ 6-8 drinks
- ○ more than 8 drinks

16. Have you/patient had a CT scan or MRI of the head during the last 12 months ?

- ○ Yes
- ○ No

FIG. 15F

Questionnaire - Alzheimer's

SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies ?

- ○ Yes, contact me.
- ○ No, I do not want to be contacted.

FIG. 15G

Questionnaire - Alzheimer's

SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies ?

- ○ Yes, contact me
- ○ No, I do not want to be contacted

FIG. 15H

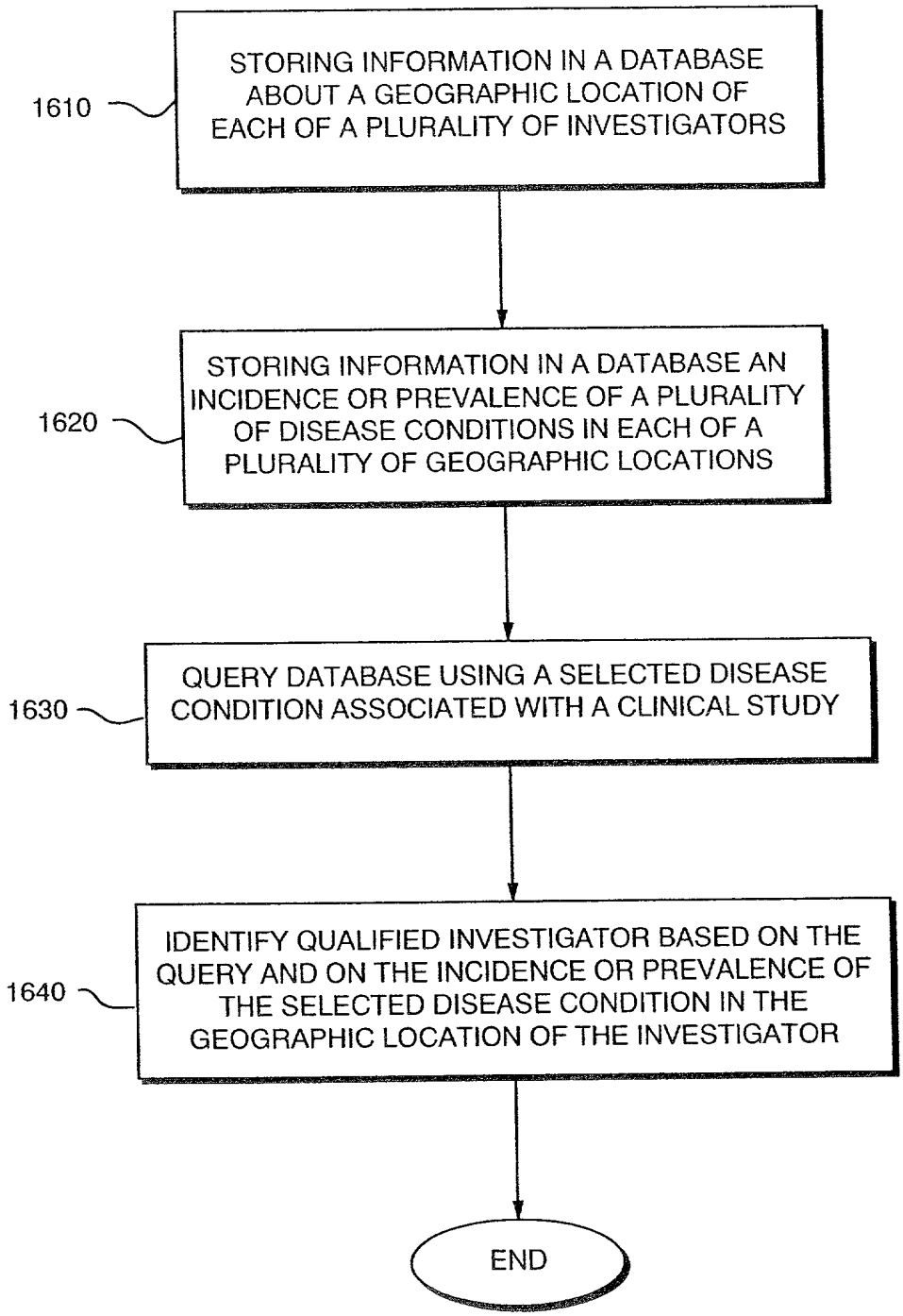

1610
STORING INFORMATION IN A DATABASE ABOUT A GEOGRAPHIC LOCATION OF EACH OF A PLURALITY OF INVESTIGATORS
1620
STORING INFORMATION IN A DATABASE AN INCIDENCE OR PREVALENCE OF A PLURALITY OF DISEASE CONDITIONS IN EACH OF A PLURALITY OF GEOGRAPHIC LOCATIONS
1630
QUERY DATABASE USING A SELECTED DISEASE CONDITION ASSOCIATED WITH A CLINICAL STUDY
1640
IDENTIFY QUALIFIED INVESTIGATOR BASED ON THE QUERY AND ON THE INCIDENCE OR PREVALENCE OF THE SELECTED DISEASE CONDITION IN THE GEOGRAPHIC LOCATION OF THE INVESTIGATOR
END

FIG. 16

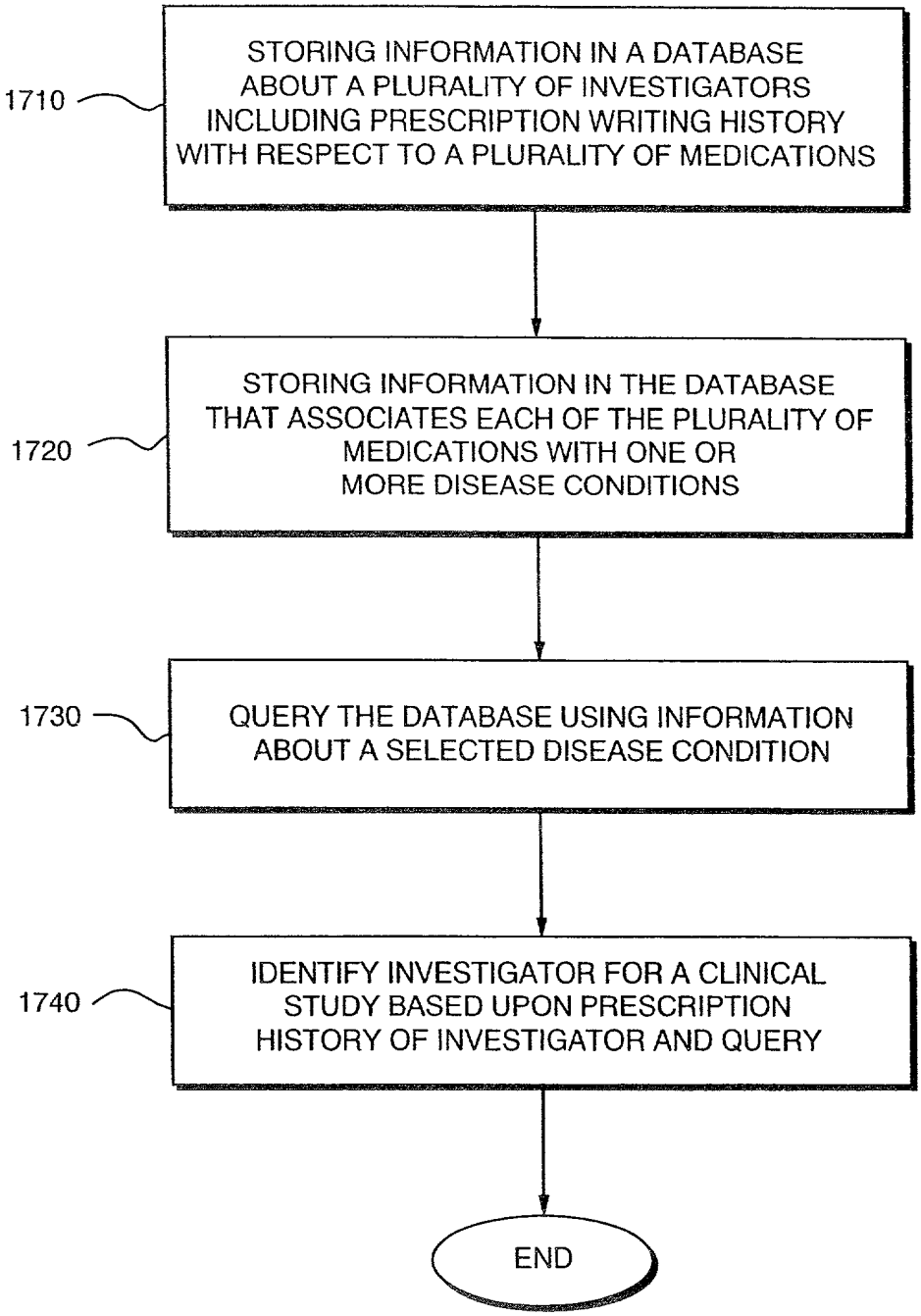

1710
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING PRESCRIPTION WRITING HISTORY WITH RESPECT TO A PLURALITY OF MEDICATIONS
1720
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES EACH OF THE PLURALITY OF MEDICATIONS WITH ONE OR MORE DISEASE CONDITIONS
1730
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
1740
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON PRESCRIPTION HISTORY OF INVESTIGATOR AND QUERY
END

FIG. 17

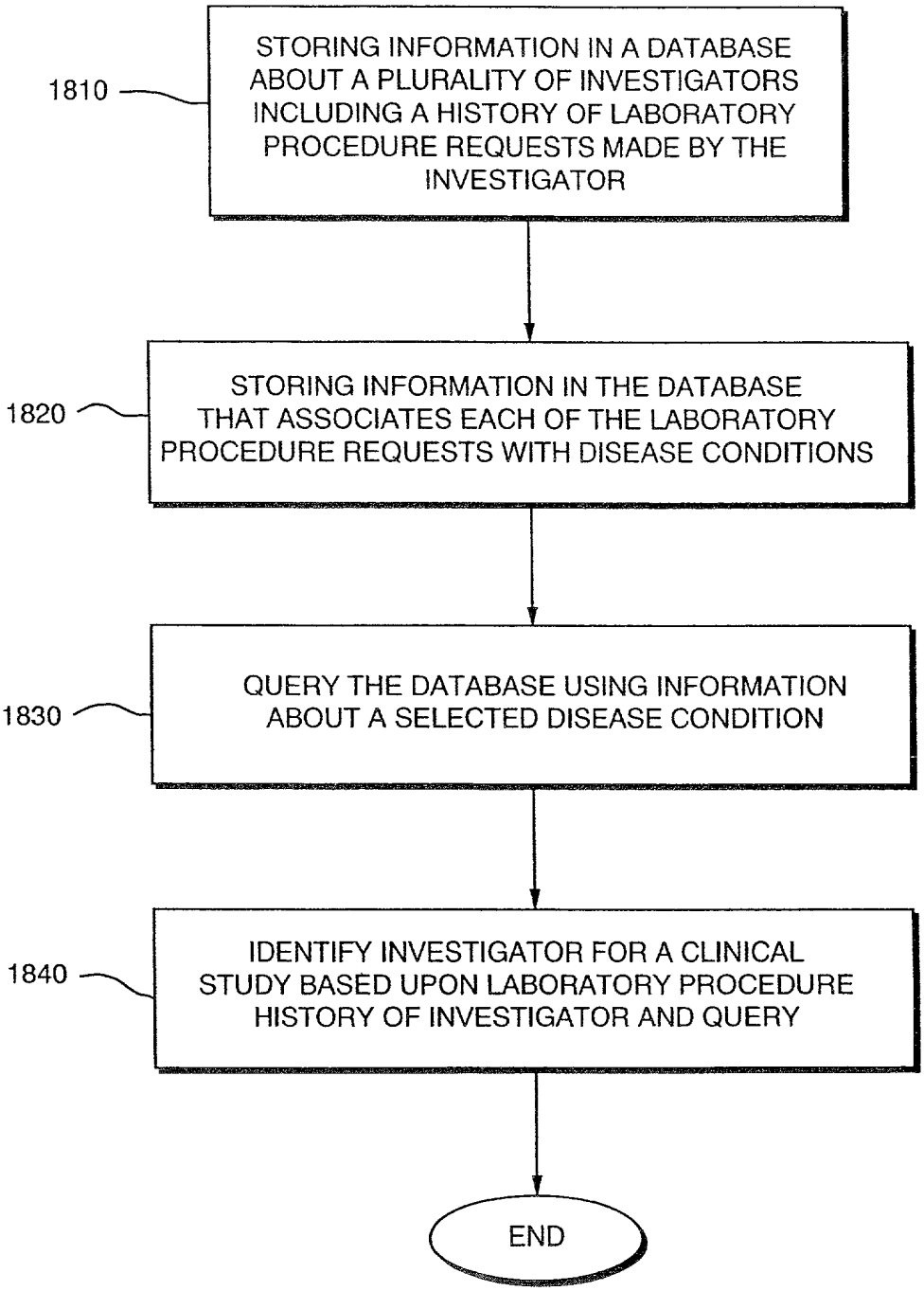

1810
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING A HISTORY OF LABORATORY PROCEDURE REQUESTS MADE BY THE INVESTIGATOR
1820
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES EACH OF THE LABORATORY PROCEDURE REQUESTS WITH DISEASE CONDITIONS
1830
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
1840
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON LABORATORY PROCEDURE HISTORY OF INVESTIGATOR AND QUERY
END

FIG. 18

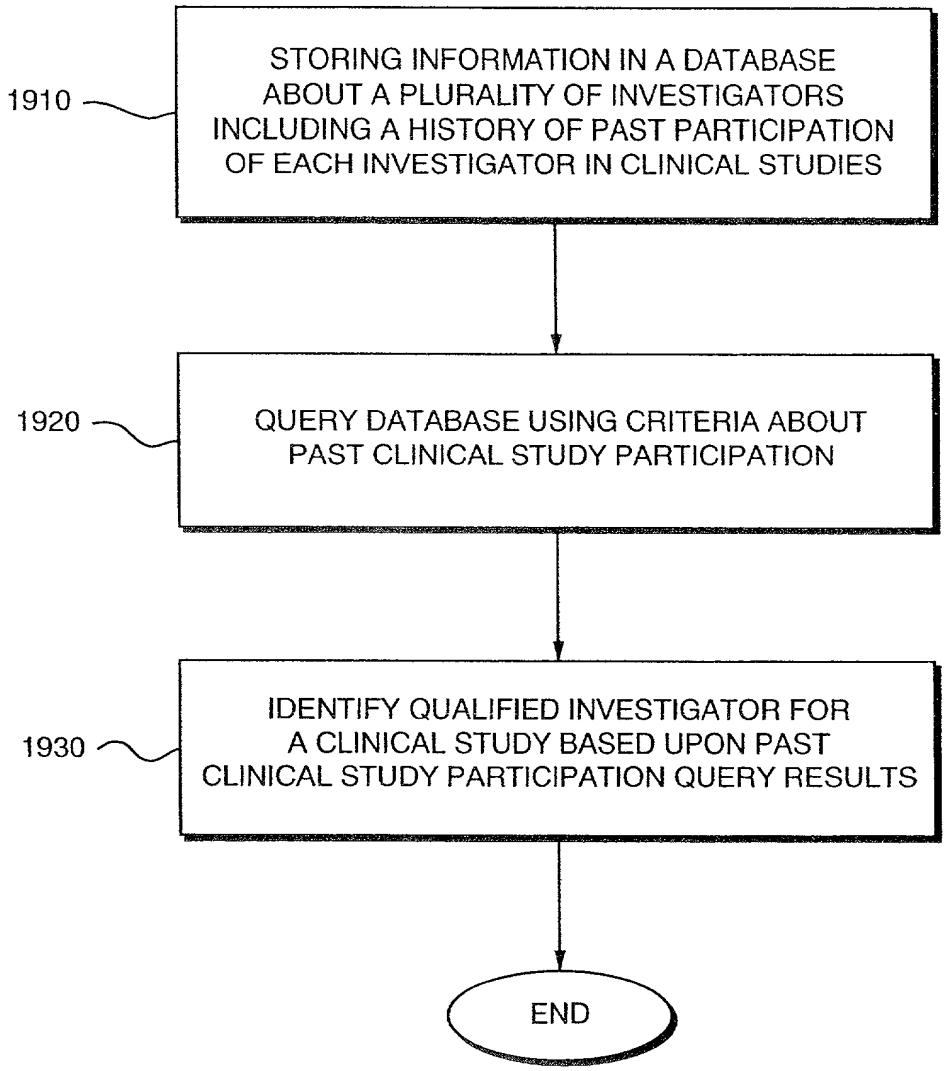

1910
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING A HISTORY OF PAST PARTICIPATION OF EACH INVESTIGATOR IN CLINICAL STUDIES
1920
QUERY DATABASE USING CRITERIA ABOUT PAST CLINICAL STUDY PARTICIPATION
1930
IDENTIFY QUALIFIED INVESTIGATOR FOR A CLINICAL STUDY BASED UPON PAST CLINICAL STUDY PARTICIPATION QUERY RESULTS
END

FIG. 19

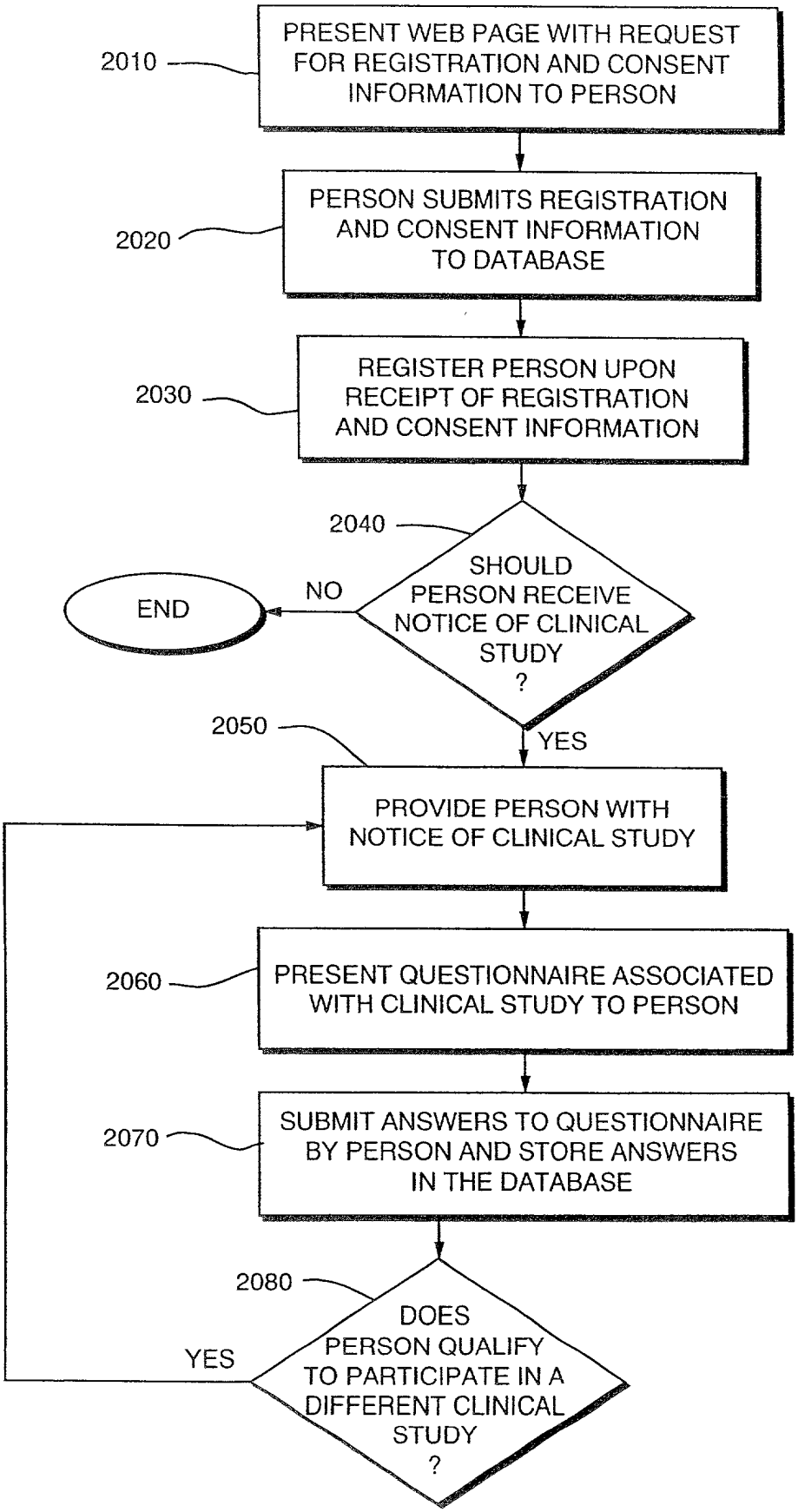

2010
PRESENT WEB PAGE WITH REQUEST FOR REGISTRATION AND CONSENT INFORMATION TO PERSON
2020
PERSON SUBMITS REGISTRATION AND CONSENT INFORMATION TO DATABASE
2030
REGISTER PERSON UPON RECEIPT OF REGISTRATION AND CONSENT INFORMATION
2040
SHOULD PERSON RECEIVE NOTICE OF CLINICAL STUDY ?
NO
END
YES
2050
PROVIDE PERSON WITH NOTICE OF CLINICAL STUDY
2060
PRESENT QUESTIONNAIRE ASSOCIATED WITH CLINICAL STUDY TO PERSON
2070
SUBMIT ANSWERS TO QUESTIONNAIRE BY PERSON AND STORE ANSWERS IN THE DATABASE
2080
DOES PERSON QUALIFY TO PARTICIPATE IN A DIFFERENT CLINICAL STUDY ?
YES

FIG. 20

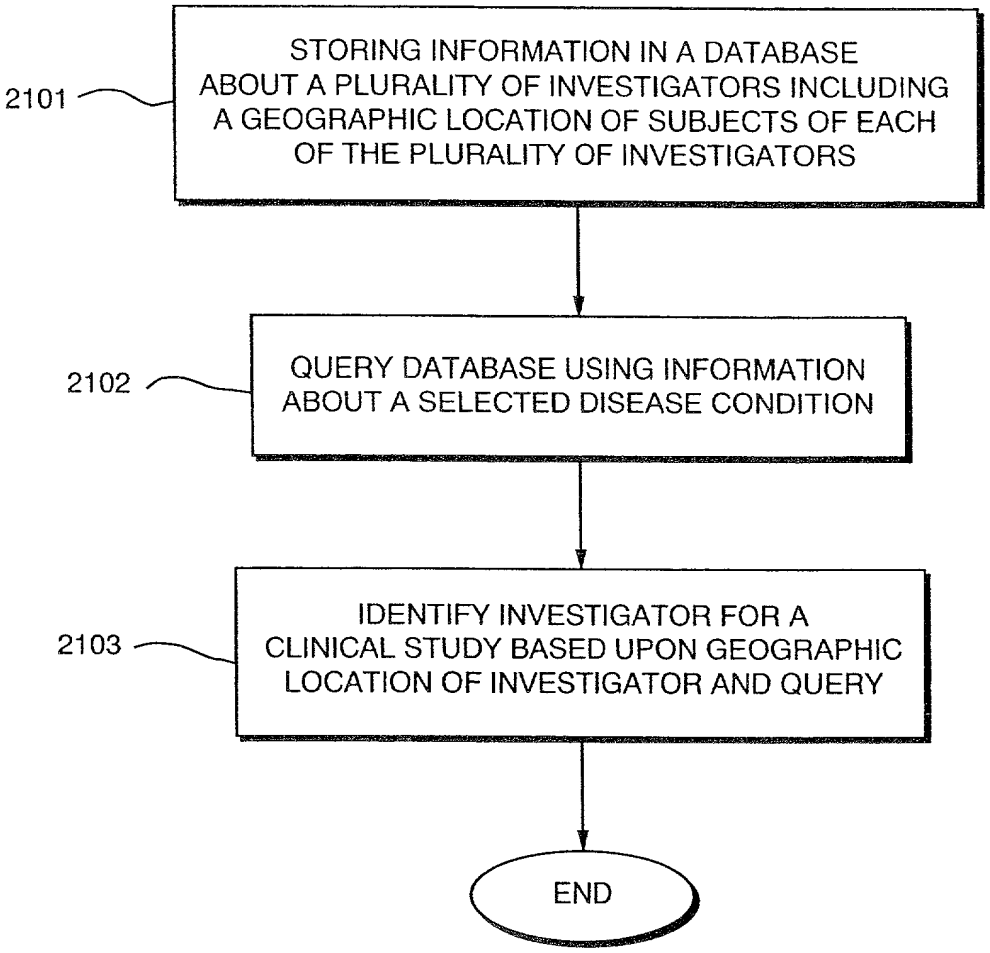

2101
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING A GEOGRAPHIC LOCATION OF SUBJECTS OF EACH OF THE PLURALITY OF INVESTIGATORS
2102
QUERY DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2103
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON GEOGRAPHIC LOCATION OF INVESTIGATOR AND QUERY
END

FIG. 21A

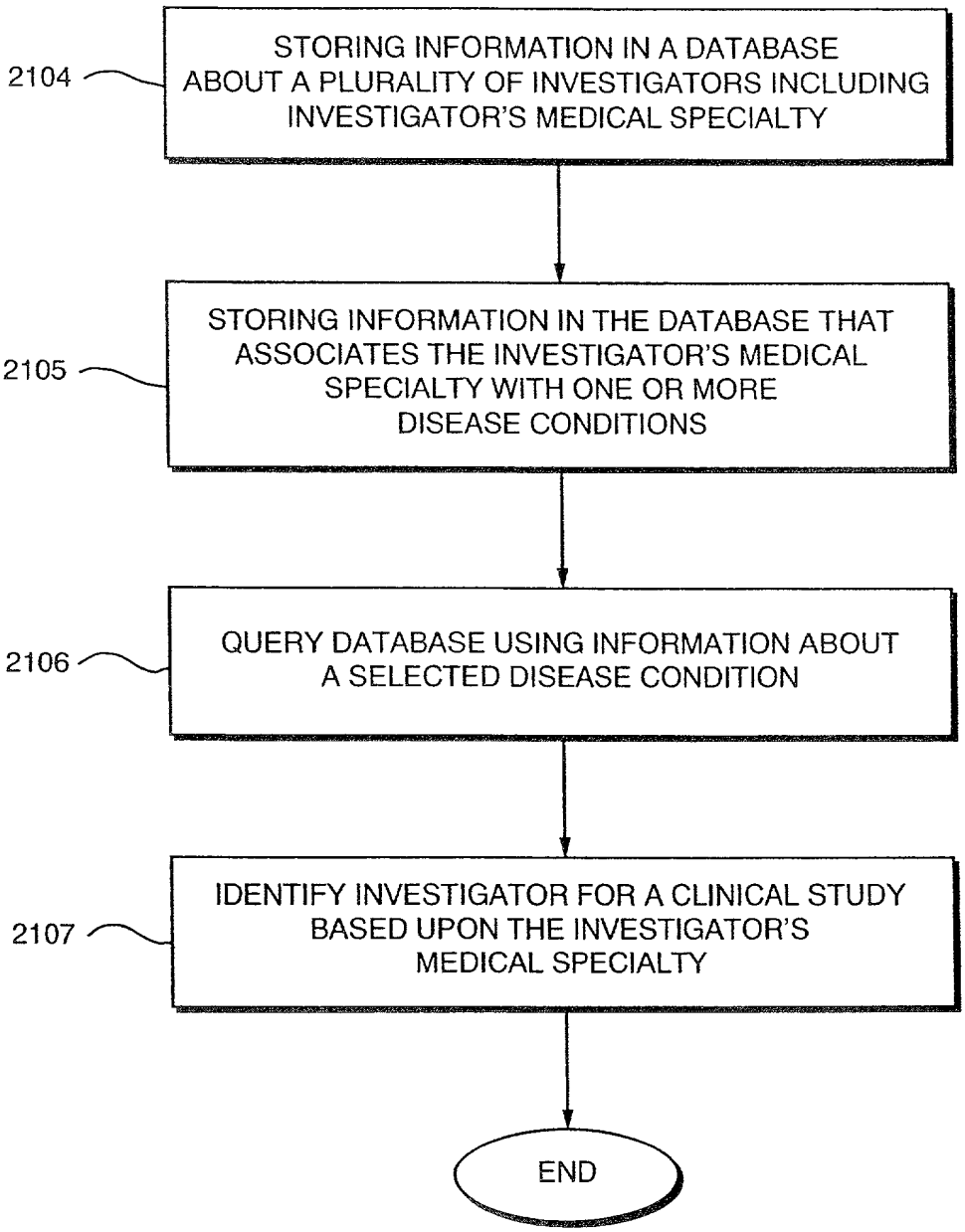

2104
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR'S MEDICAL SPECIALTY
2105
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES THE INVESTIGATOR'S MEDICAL SPECIALTY WITH ONE OR MORE DISEASE CONDITIONS
2106
QUERY DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2107
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON THE INVESTIGATOR'S MEDICAL SPECIALTY
END

FIG. 21B

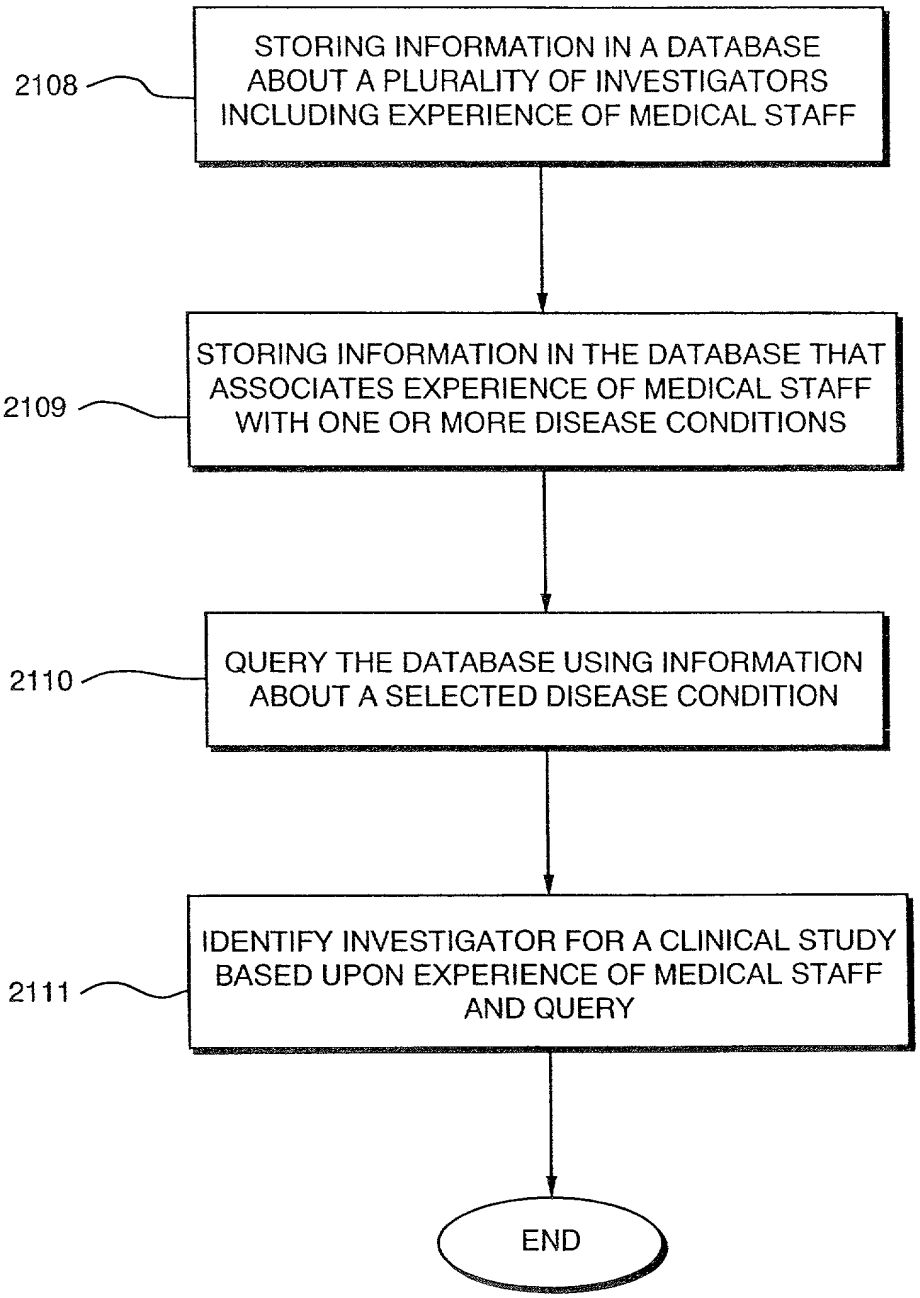

2108
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING EXPERIENCE OF MEDICAL STAFF
2109
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES EXPERIENCE OF MEDICAL STAFF WITH ONE OR MORE DISEASE CONDITIONS
2110
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2111
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON EXPERIENCE OF MEDICAL STAFF AND QUERY
END

FIG. 21C

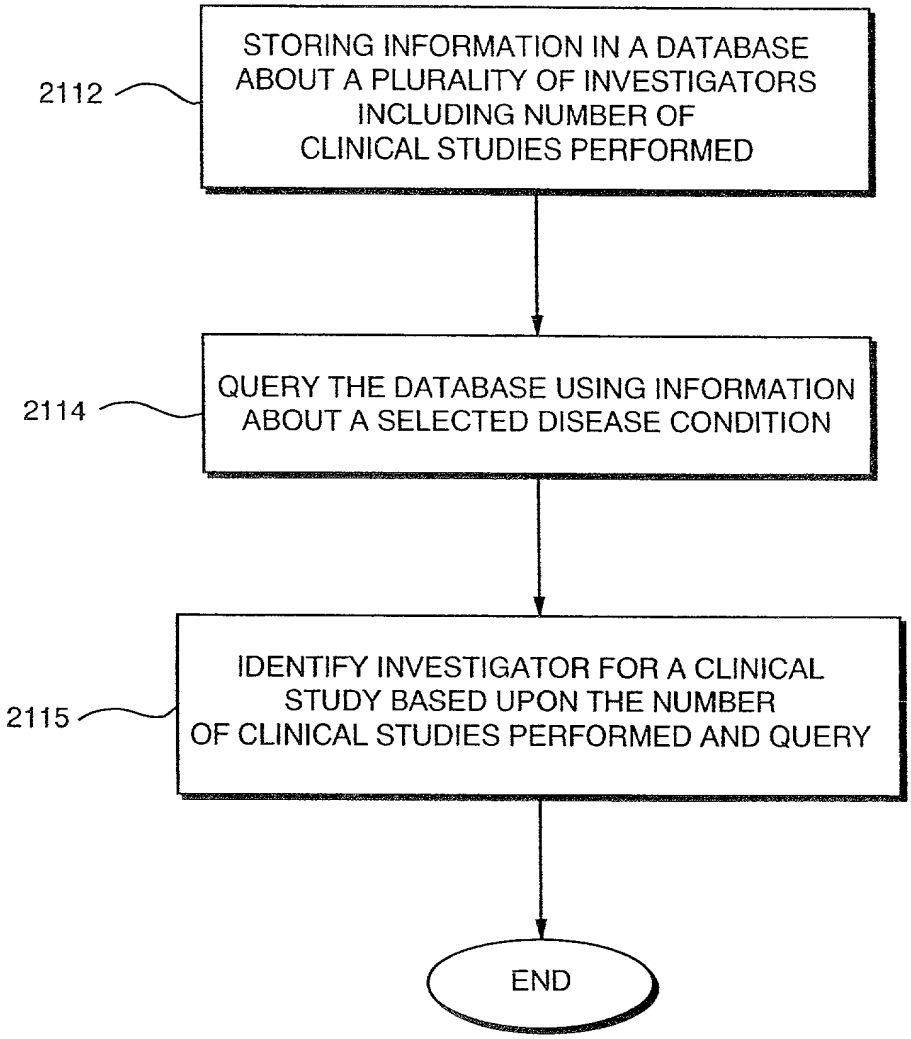

2112
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING NUMBER OF CLINICAL STUDIES PERFORMED
2114
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2115
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON THE NUMBER OF CLINICAL STUDIES PERFORMED AND QUERY
END

FIG. 21D

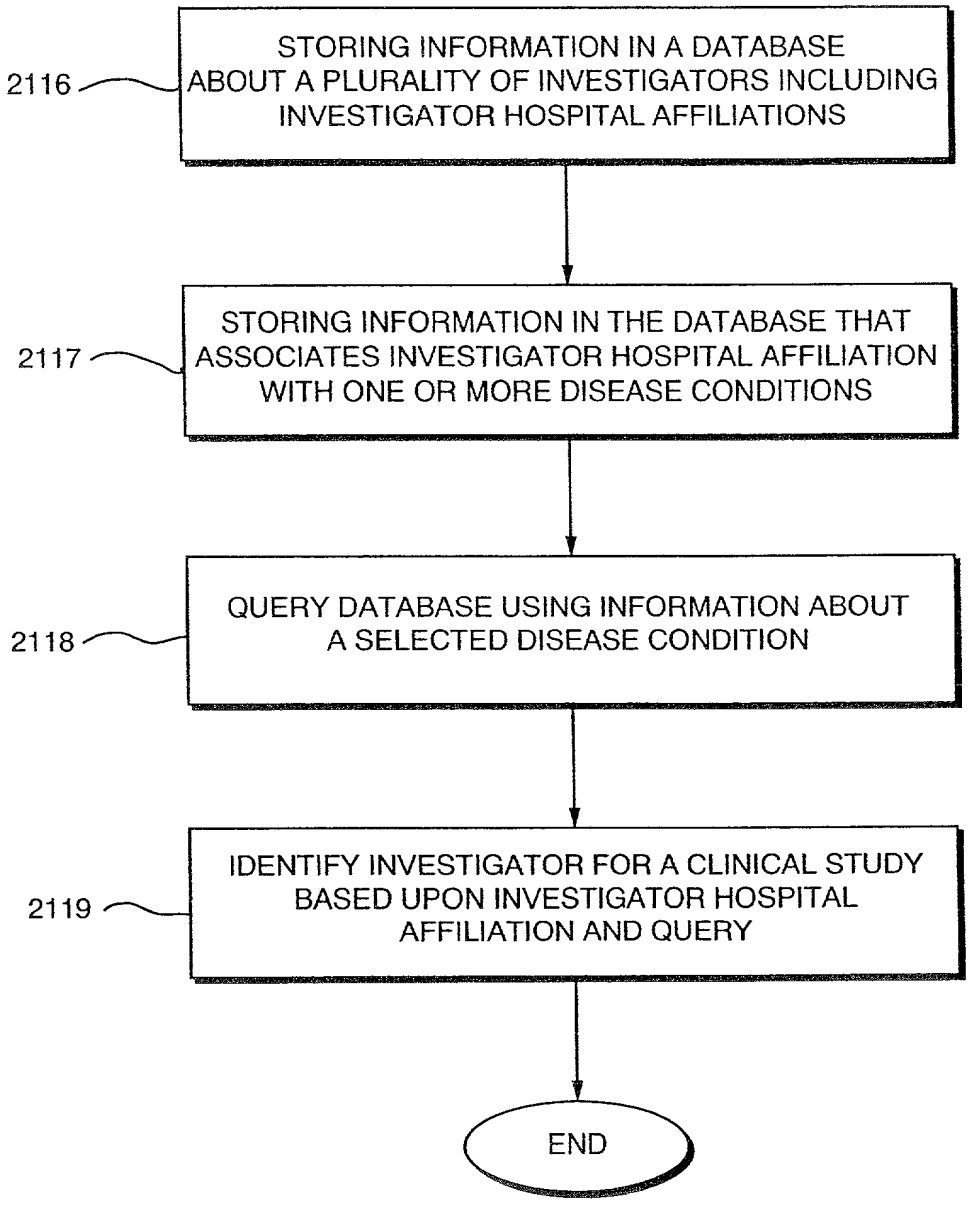

2116
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR HOSPITAL AFFILIATIONS
2117
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR HOSPITAL AFFILIATION WITH ONE OR MORE DISEASE CONDITIONS
2118
QUERY DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2119
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR HOSPITAL AFFILIATION AND QUERY
END

FIG. 21E

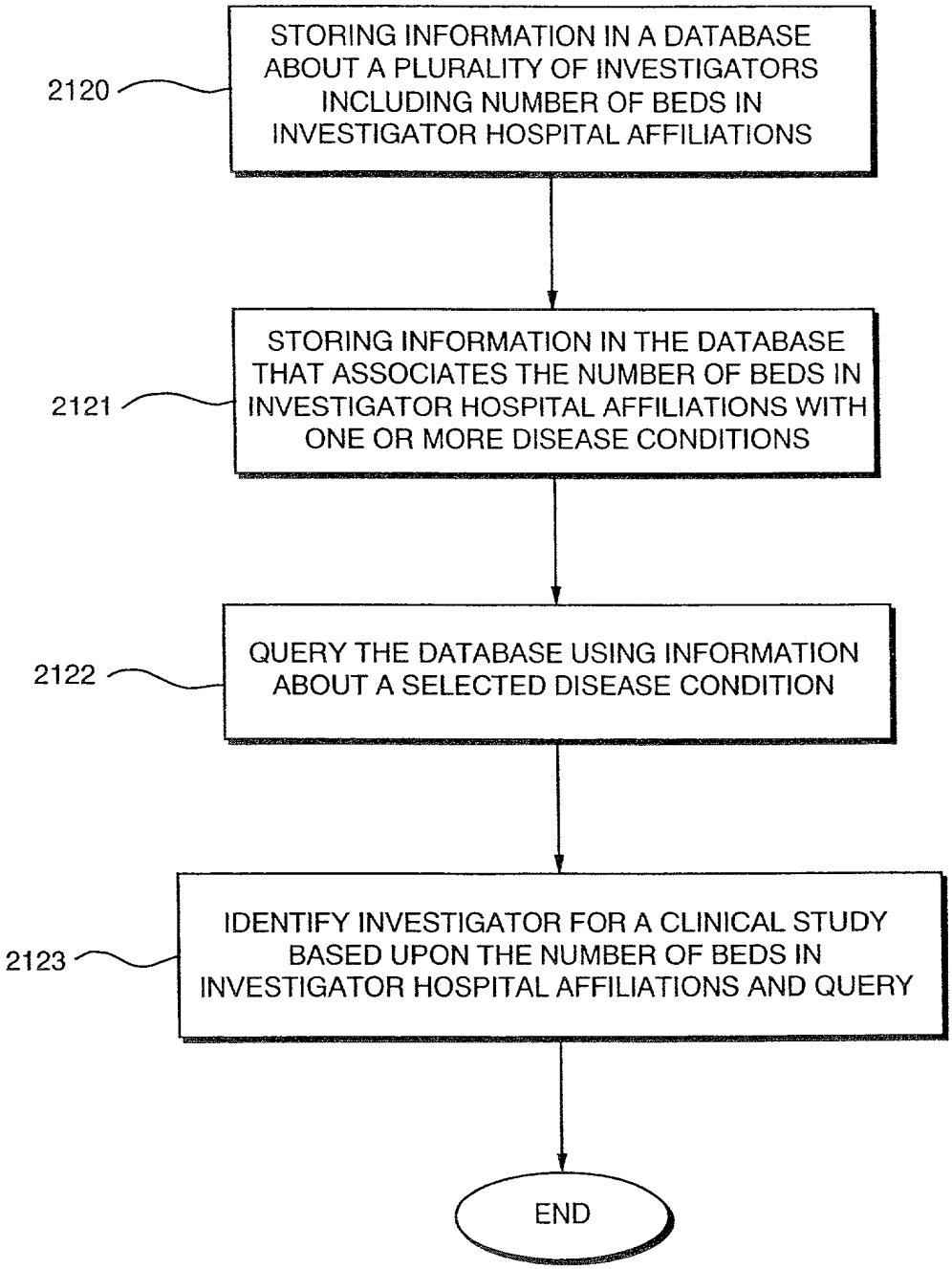

2120
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING NUMBER OF BEDS IN INVESTIGATOR HOSPITAL AFFILIATIONS
2121
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES THE NUMBER OF BEDS IN INVESTIGATOR HOSPITAL AFFILIATIONS WITH ONE OR MORE DISEASE CONDITIONS
2122
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2123
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON THE NUMBER OF BEDS IN INVESTIGATOR HOSPITAL AFFILIATIONS AND QUERY
END

FIG. 21F

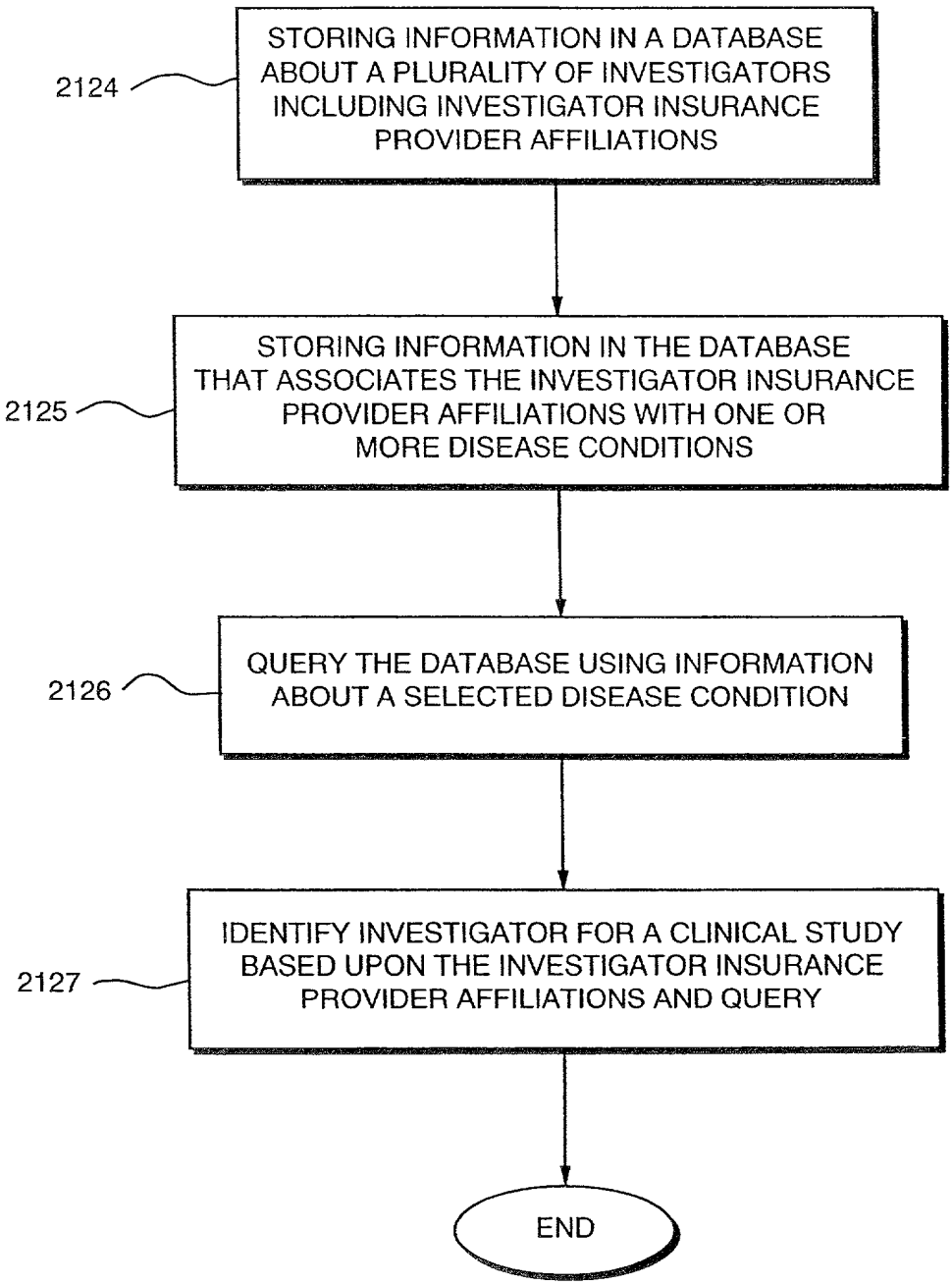

2124
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR INSURANCE PROVIDER AFFILIATIONS
2125
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES THE INVESTIGATOR INSURANCE PROVIDER AFFILIATIONS WITH ONE OR MORE DISEASE CONDITIONS
2126
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2127
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON THE INVESTIGATOR INSURANCE PROVIDER AFFILIATIONS AND QUERY
END

FIG. 21G

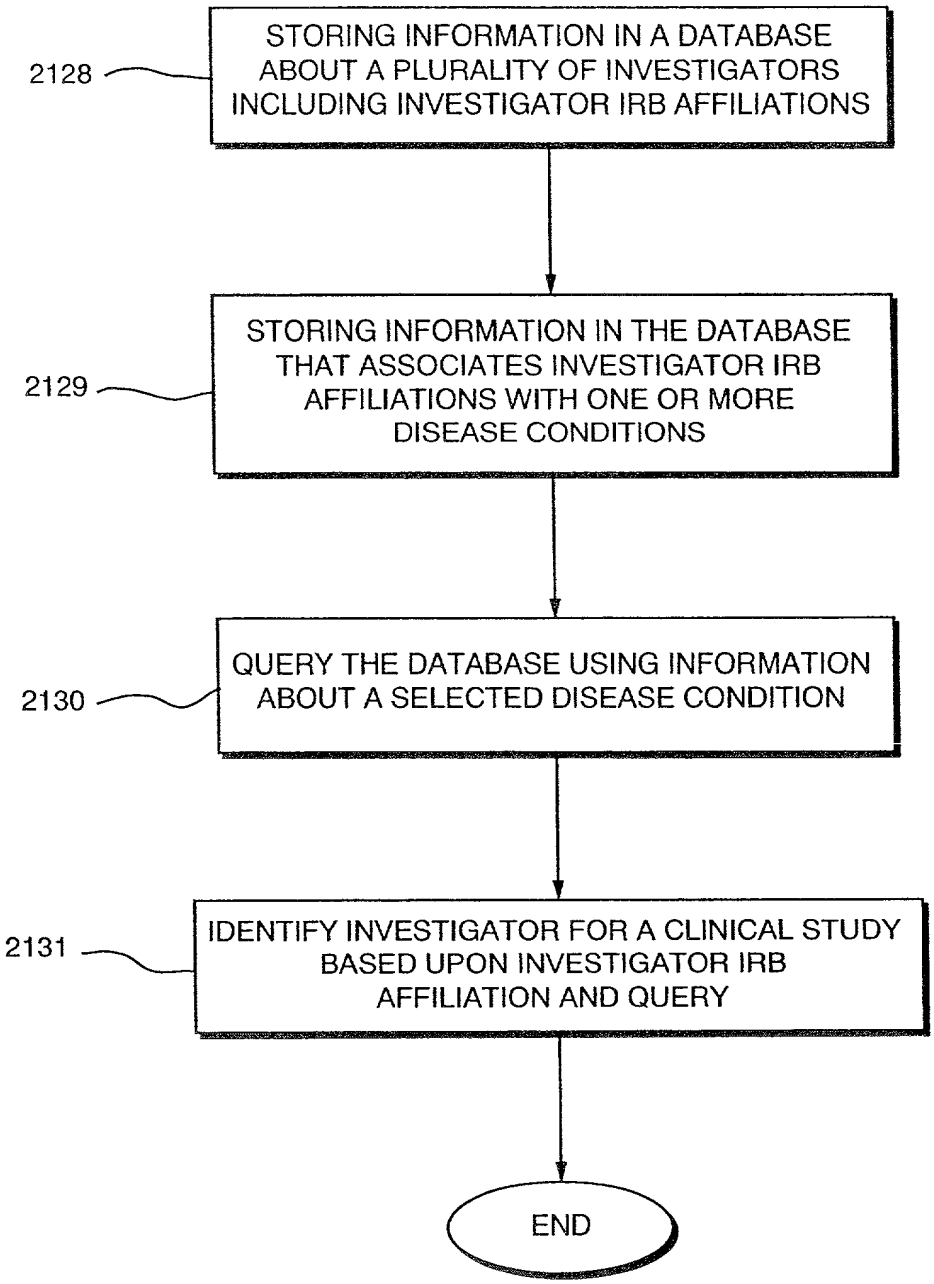

2128
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR IRB AFFILIATIONS
2129
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR IRB AFFILIATIONS WITH ONE OR MORE DISEASE CONDITIONS
2130
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2131
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR IRB AFFILIATION AND QUERY
END

FIG. 21H

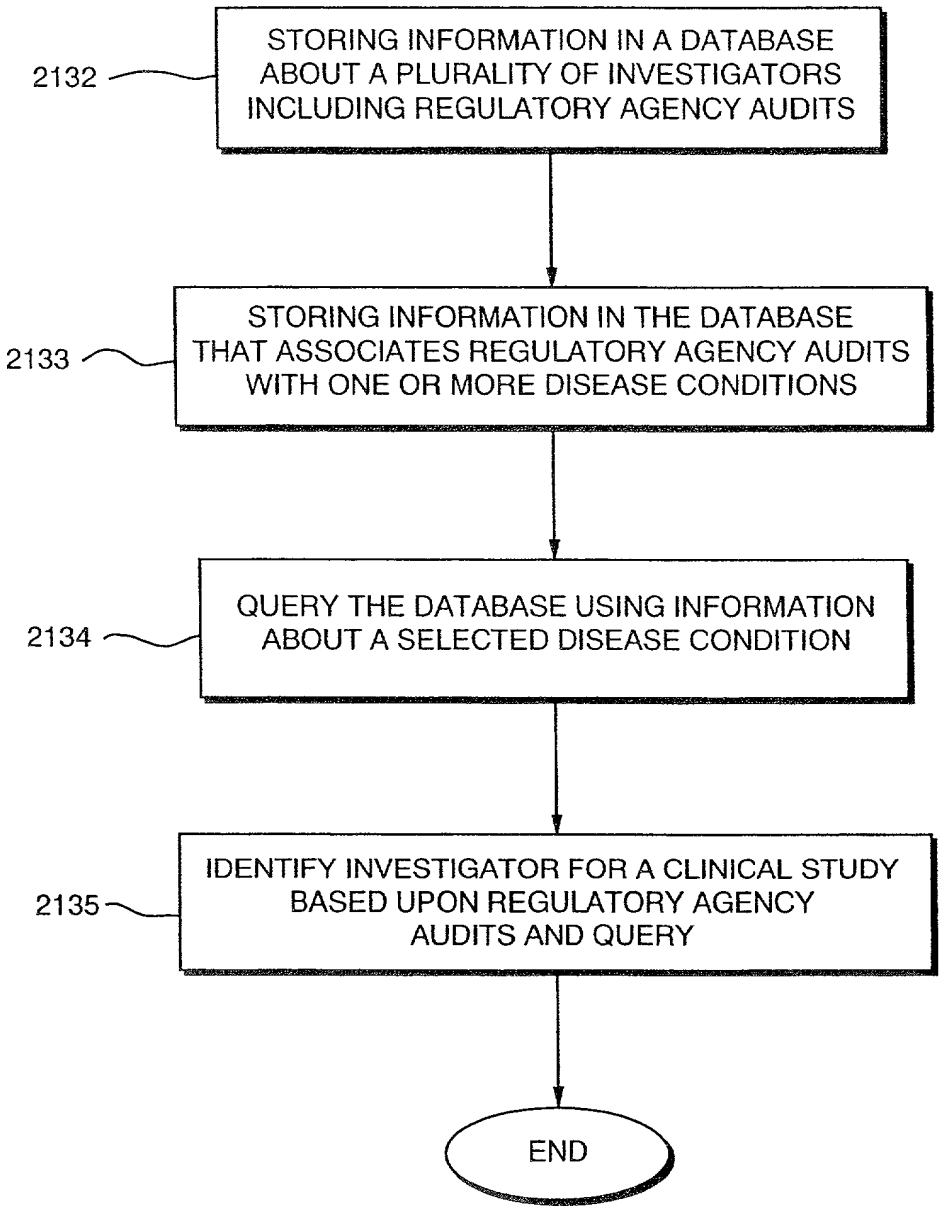

2132
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING REGULATORY AGENCY AUDITS
2133
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES REGULATORY AGENCY AUDITS WITH ONE OR MORE DISEASE CONDITIONS
2134
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2135
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON REGULATORY AGENCY AUDITS AND QUERY
END

FIG. 21I

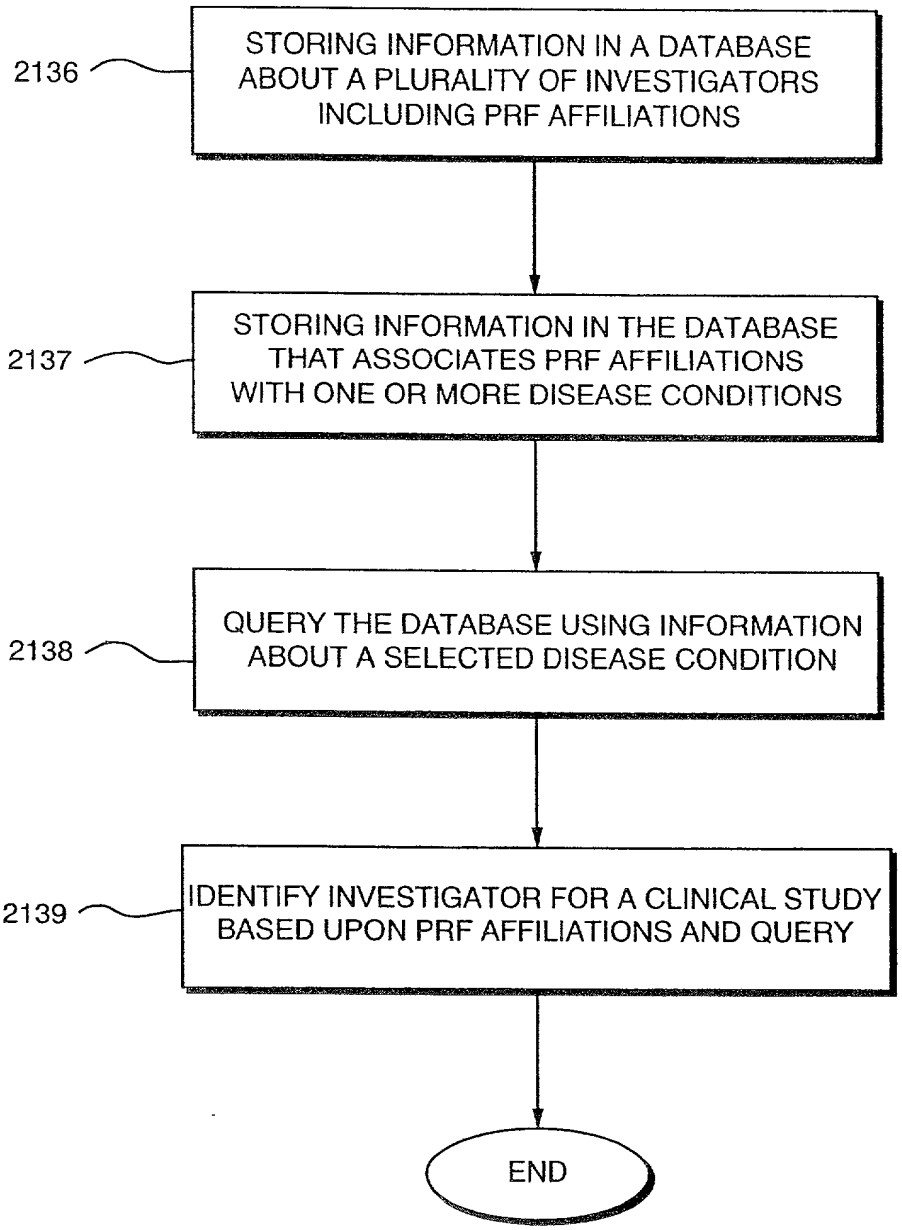

2136
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING PRF AFFILIATIONS
2137
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES PRF AFFILIATIONS WITH ONE OR MORE DISEASE CONDITIONS
2138
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2139
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON PRF AFFILIATIONS AND QUERY
END

FIG. 21J

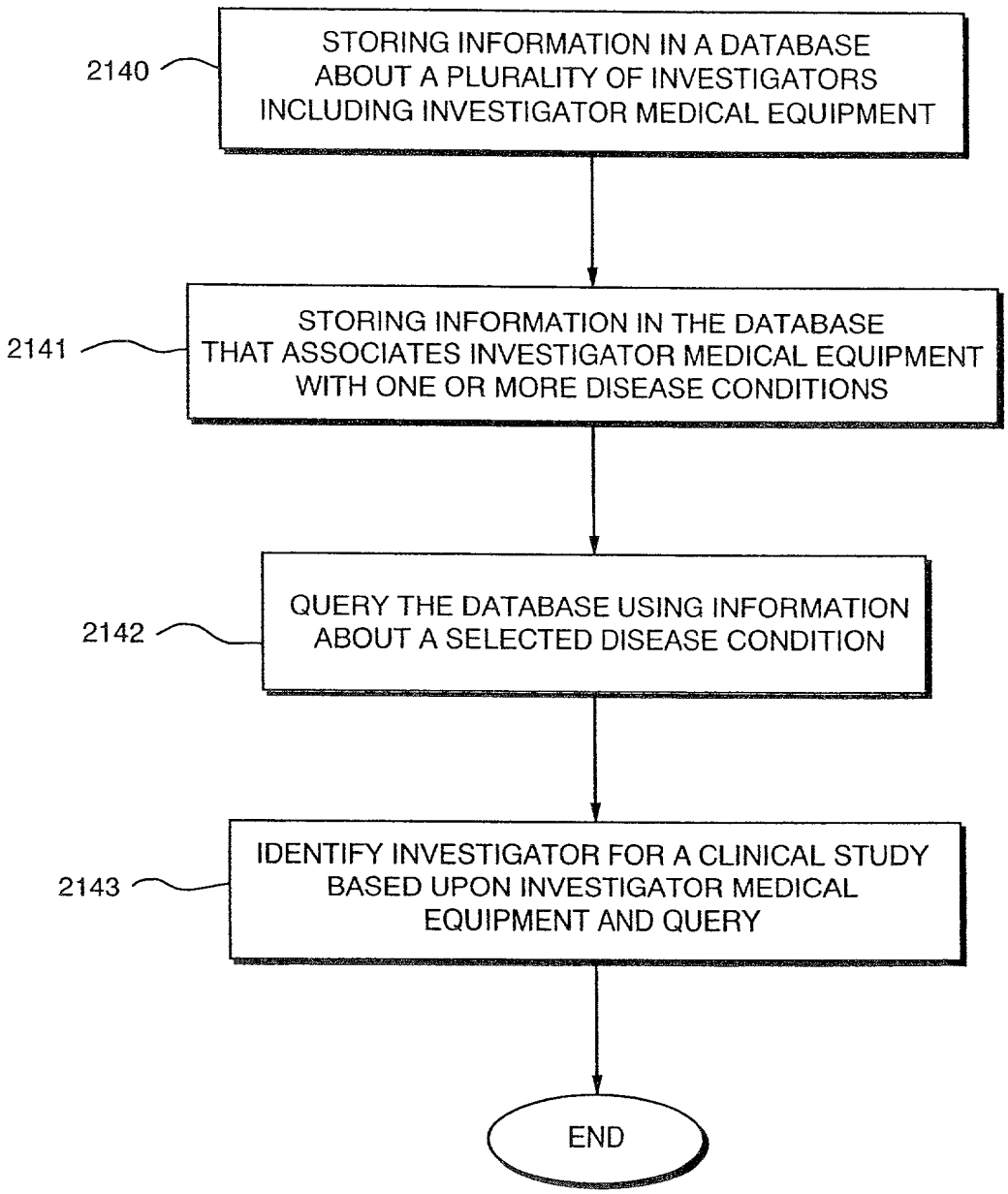

2140
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR MEDICAL EQUIPMENT
2141
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR MEDICAL EQUIPMENT WITH ONE OR MORE DISEASE CONDITIONS
2142
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2143
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR MEDICAL EQUIPMENT AND QUERY
END

FIG. 21K

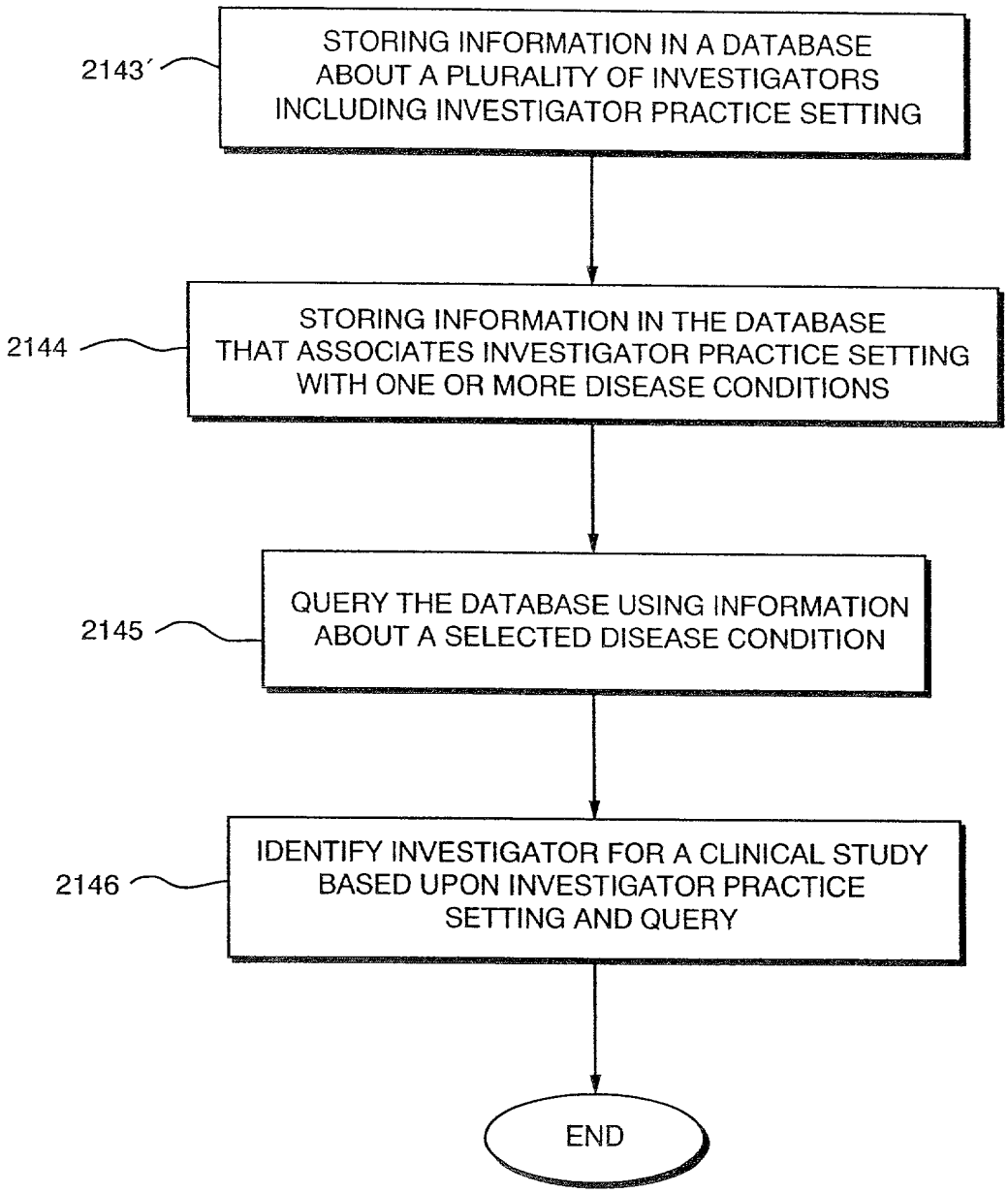

2143'
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR PRACTICE SETTING
2144
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR PRACTICE SETTING WITH ONE OR MORE DISEASE CONDITIONS
2145
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2146
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR PRACTICE SETTING AND QUERY
END

FIG. 21L

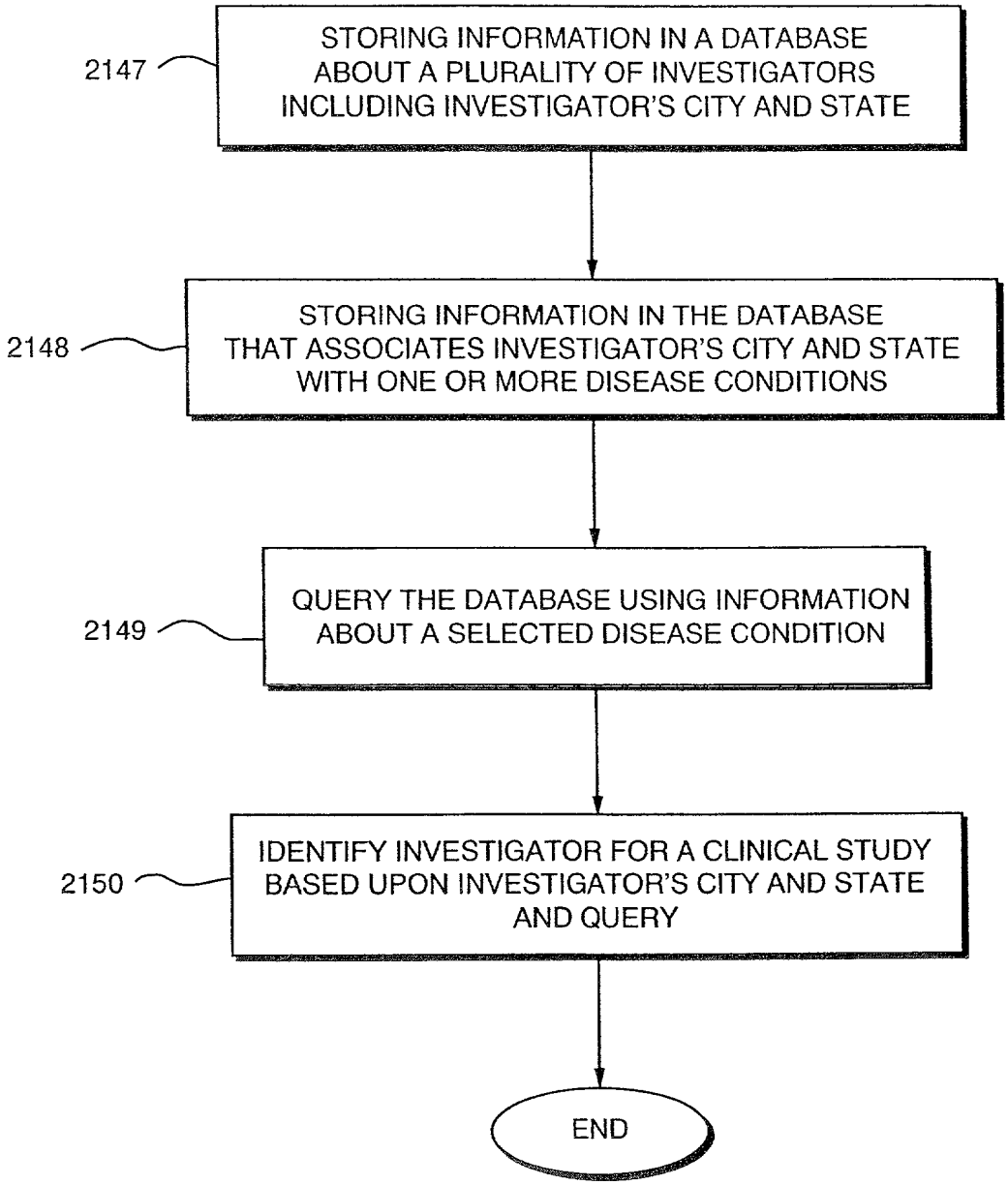

2147
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR'S CITY AND STATE
2148
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR'S CITY AND STATE WITH ONE OR MORE DISEASE CONDITIONS
2149
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2150
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR'S CITY AND STATE AND QUERY
END

FIG. 21M

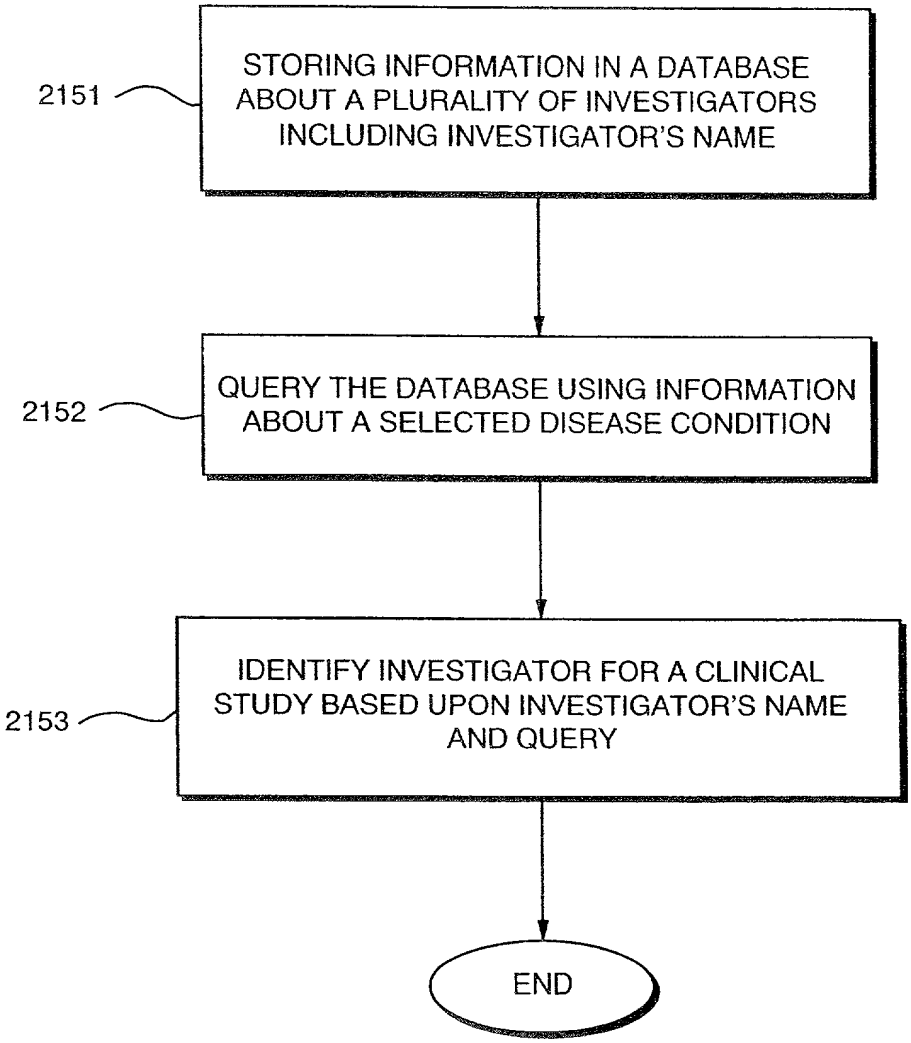

2151
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR'S NAME
2152
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2153
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR'S NAME AND QUERY
END

FIG. 21N

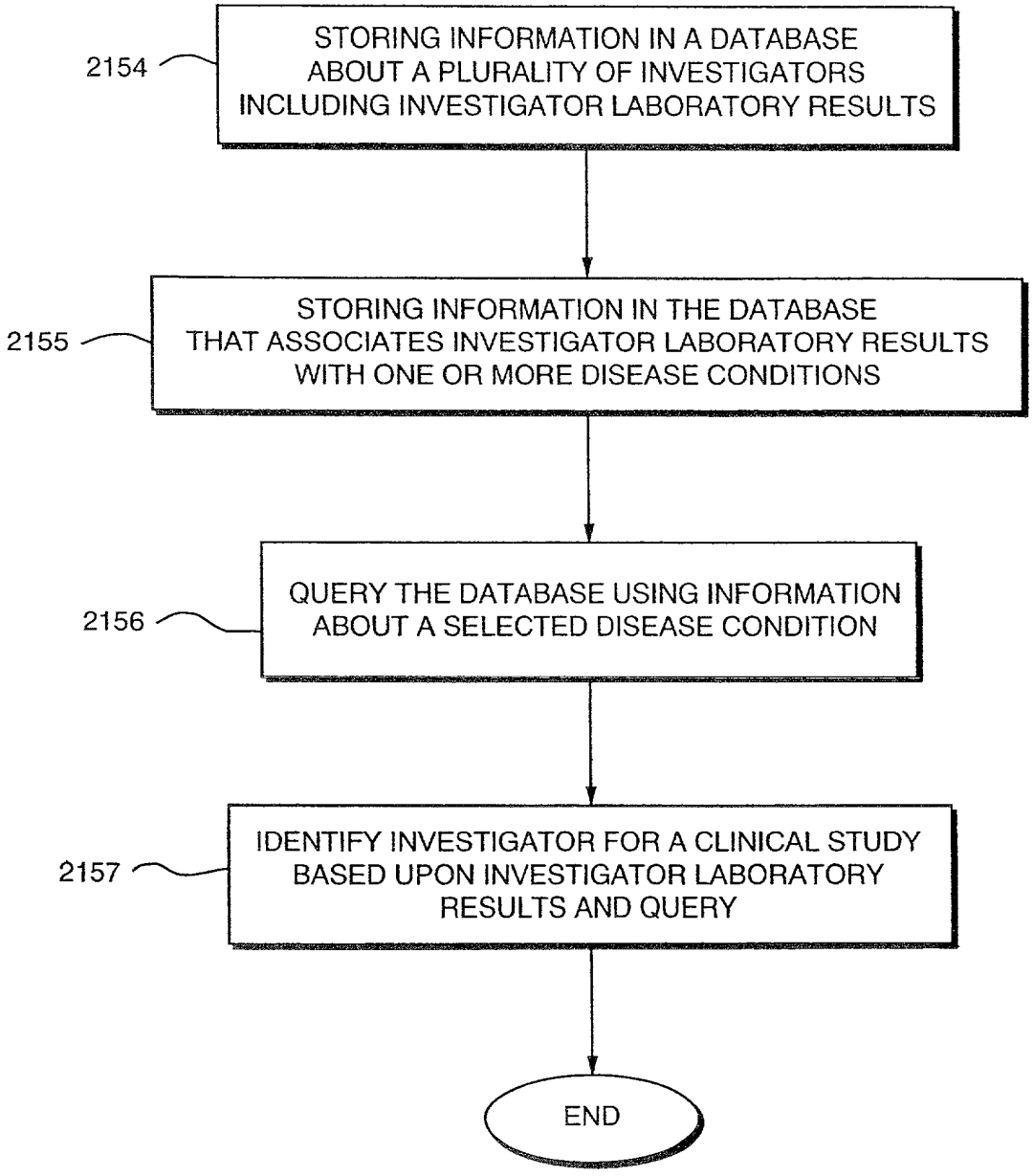

2154
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR LABORATORY RESULTS
2155
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR LABORATORY RESULTS WITH ONE OR MORE DISEASE CONDITIONS
2156
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2157
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR LABORATORY RESULTS AND QUERY
END

FIG. 21O

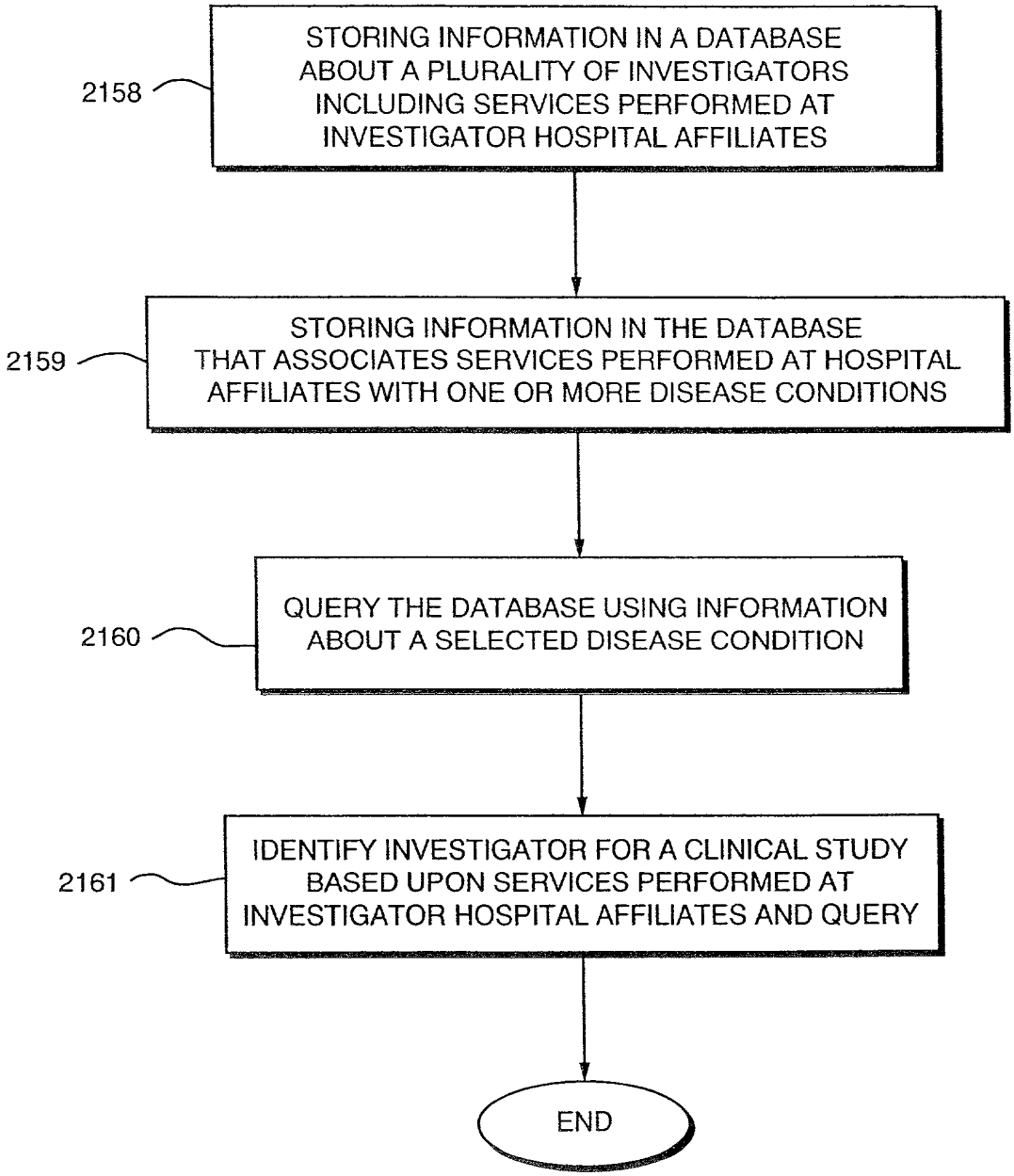

2158
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING SERVICES PERFORMED AT INVESTIGATOR HOSPITAL AFFILIATES
2159
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES SERVICES PERFORMED AT HOSPITAL AFFILIATES WITH ONE OR MORE DISEASE CONDITIONS
2160
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2161
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON SERVICES PERFORMED AT INVESTIGATOR HOSPITAL AFFILIATES AND QUERY
END

FIG. 21P

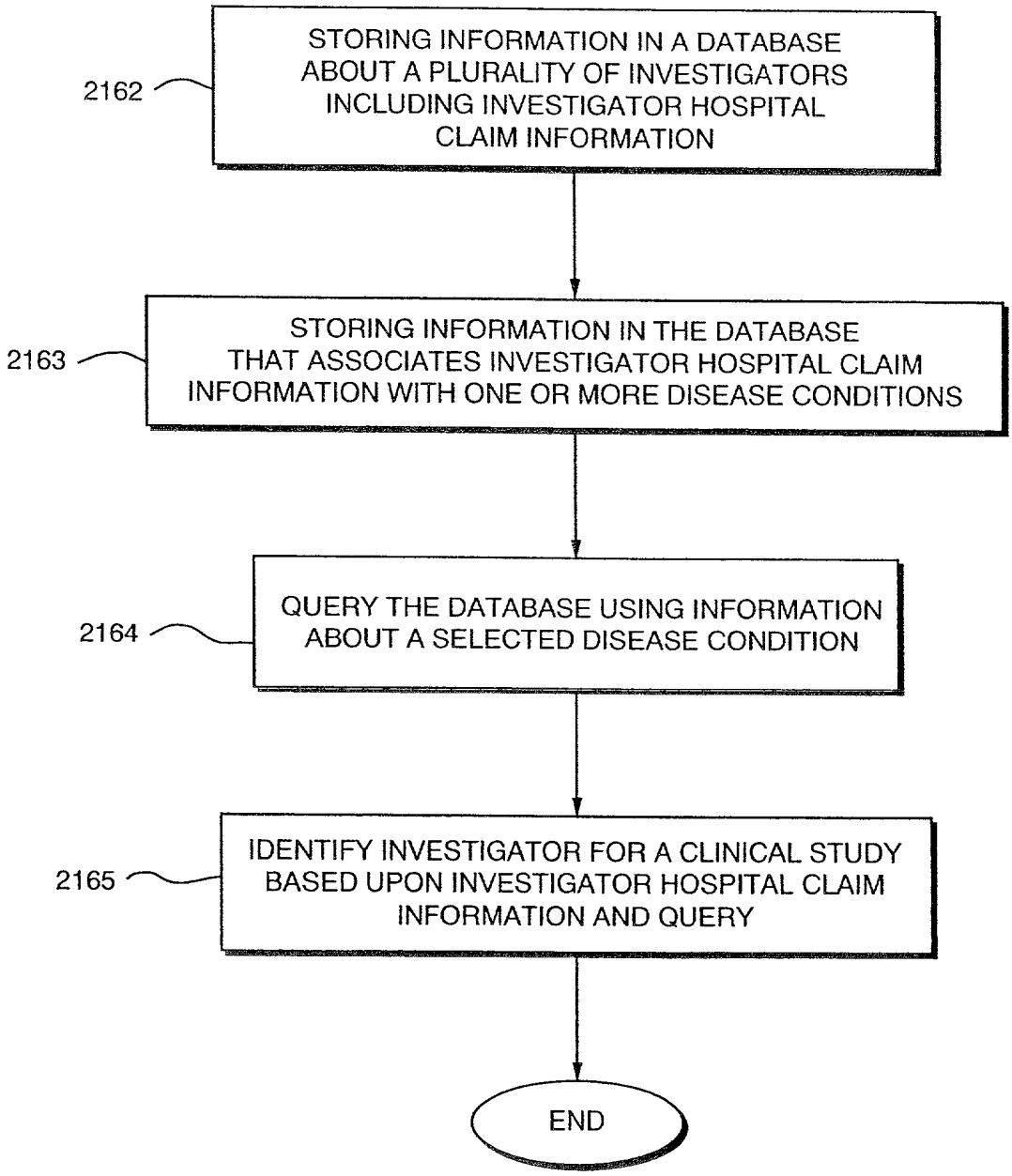

2162
STORING INFORMATION IN A DATABASE ABOUT A PLURALITY OF INVESTIGATORS INCLUDING INVESTIGATOR HOSPITAL CLAIM INFORMATION
2163
STORING INFORMATION IN THE DATABASE THAT ASSOCIATES INVESTIGATOR HOSPITAL CLAIM INFORMATION WITH ONE OR MORE DISEASE CONDITIONS
2164
QUERY THE DATABASE USING INFORMATION ABOUT A SELECTED DISEASE CONDITION
2165
IDENTIFY INVESTIGATOR FOR A CLINICAL STUDY BASED UPON INVESTIGATOR HOSPITAL CLAIM INFORMATION AND QUERY
END

FIG. 21Q

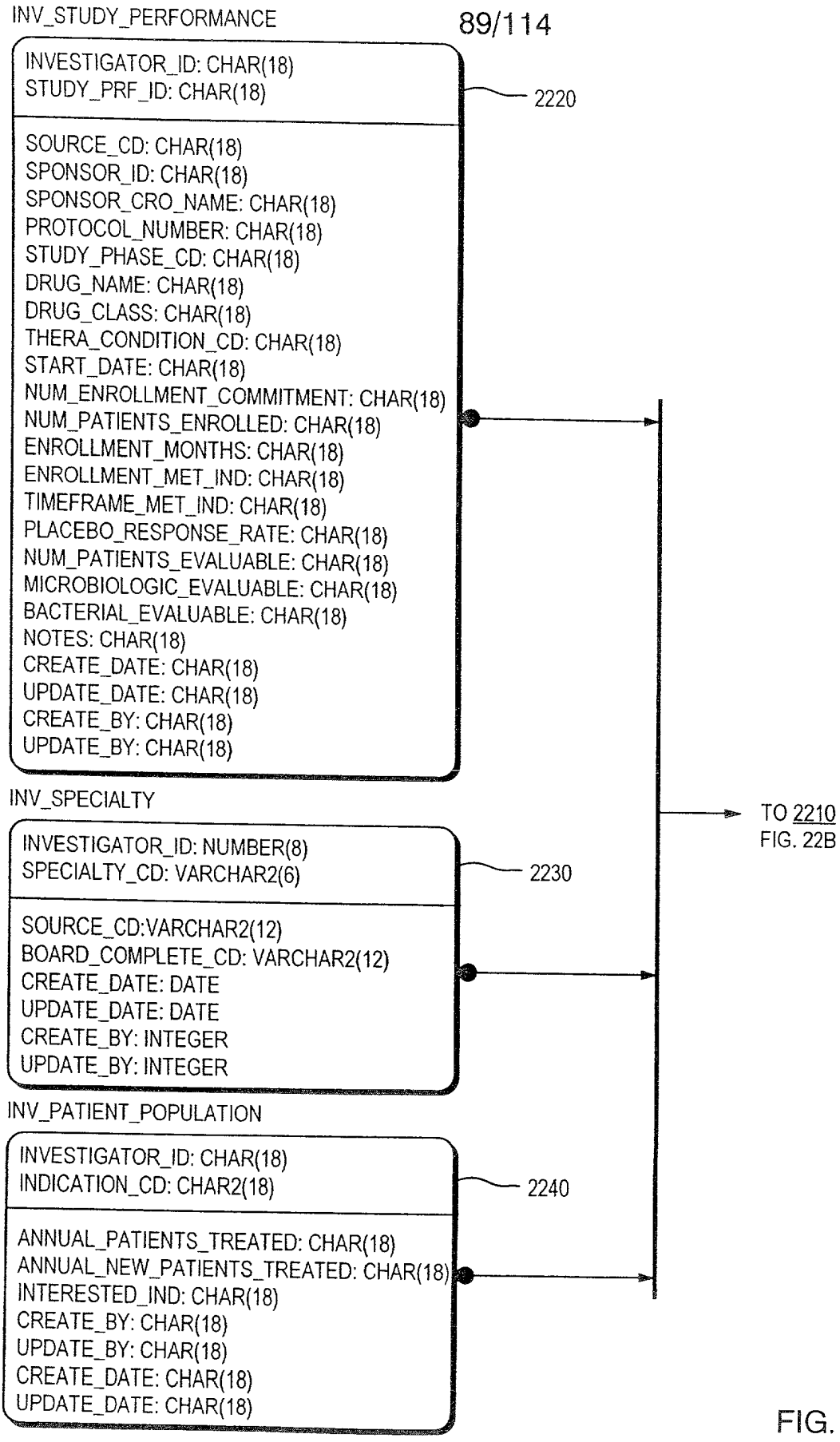

INV_STUDY_PERFORMANCE
INVESTIGATOR_ID: CHAR(18)
STUDY_PRF_ID: CHAR(18)
2220
SOURCE_CD: CHAR(18)
SPONSOR_ID: CHAR(18)
SPONSOR_CRO_NAME: CHAR(18)
PROTOCOL_NUMBER: CHAR(18)
STUDY_PHASE_CD: CHAR(18)
DRUG_NAME: CHAR(18)
DRUG_CLASS: CHAR(18)
THERA_CONDITION_CD: CHAR(18)
START_DATE: CHAR(18)
NUM_ENROLLMENT_COMMITMENT: CHAR(18)
NUM_PATIENTS_ENROLLED: CHAR(18)
ENROLLMENT_MONTHS: CHAR(18)
ENROLLMENT_MET_IND: CHAR(18)
TIMEFRAME_MET_IND: CHAR(18)
PLACEBO_RESPONSE_RATE: CHAR(18)
NUM_PATIENTS_EVALUABLE: CHAR(18)
MICROBIOLOGIC_EVALUABLE: CHAR(18)
BACTERIAL_EVALUABLE: CHAR(18)
NOTES: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
INV_SPECIALTY
INVESTIGATOR_ID: NUMBER(8)
SPECIALTY_CD: VARCHAR2(6)
2230
SOURCE_CD:VARCHAR2(12)
BOARD_COMPLETE_CD: VARCHAR2(12)
CREATE_DATE: DATE
UPDATE_DATE: DATE
CREATE_BY: INTEGER
UPDATE_BY: INTEGER
INV_PATIENT_POPULATION
INVESTIGATOR_ID: CHAR(18)
INDICATION_CD: CHAR2(18)
2240
ANNUAL_PATIENTS_TREATED: CHAR(18)
ANNUAL_NEW_PATIENTS_TREATED: CHAR(18)
INTERESTED_IND: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
TO 2210
FIG. 22B

FIG. 22A

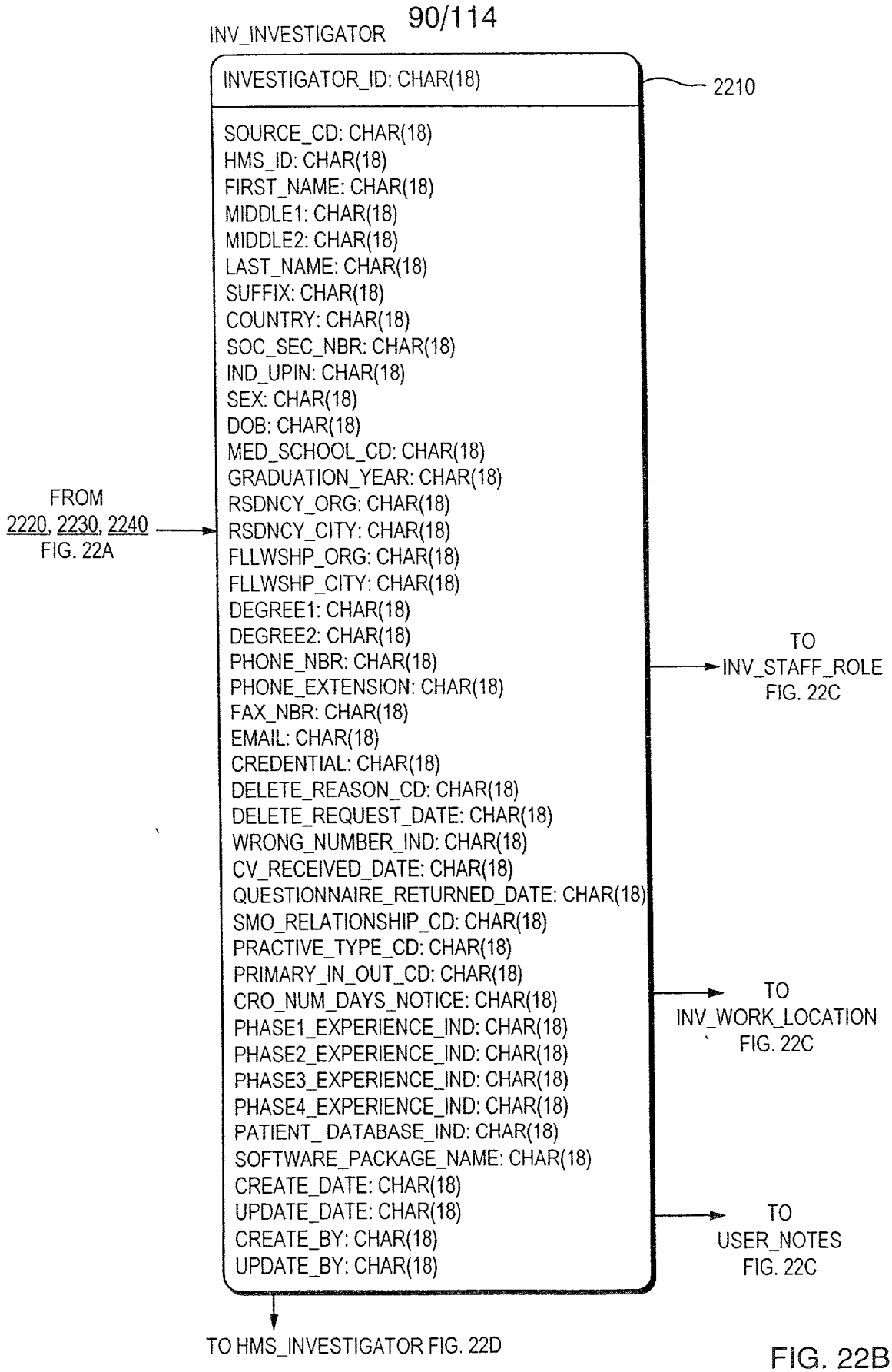

INV_INVESTIGATOR
INVESTIGATOR_ID: CHAR(18)
2210
SOURCE_CD: CHAR(18)
HMS_ID: CHAR(18)
FIRST_NAME: CHAR(18)
MIDDLE1: CHAR(18)
MIDDLE2: CHAR(18)
LAST_NAME: CHAR(18)
SUFFIX: CHAR(18)
COUNTRY: CHAR(18)
SOC_SEC_NBR: CHAR(18)
IND_UPIN: CHAR(18)
SEX: CHAR(18)
DOB: CHAR(18)
MED_SCHOOL_CD: CHAR(18)
GRADUATION_YEAR: CHAR(18)
RSDNCY_ORG: CHAR(18)
RSDNCY_CITY: CHAR(18)
FLLWSHP_ORG: CHAR(18)
FLLWSHP_CITY: CHAR(18)
DEGREE1: CHAR(18)
DEGREE2: CHAR(18)
PHONE_NBR: CHAR(18)
PHONE_EXTENSION: CHAR(18)
FAX_NBR: CHAR(18)
EMAIL: CHAR(18)
CREDENTIAL: CHAR(18)
DELETE_REASON_CD: CHAR(18)
DELETE_REQUEST_DATE: CHAR(18)
WRONG_NUMBER_IND: CHAR(18)
CV_RECEIVED_DATE: CHAR(18)
QUESTIONNAIRE_RETURNED_DATE: CHAR(18)
SMO_RELATIONSHIP_CD: CHAR(18)
PRACTIVE_TYPE_CD: CHAR(18)
PRIMARY_IN_OUT_CD: CHAR(18)
CRO_NUM_DAYS_NOTICE: CHAR(18)
PHASE1_EXPERIENCE_IND: CHAR(18)
PHASE2_EXPERIENCE_IND: CHAR(18)
PHASE3_EXPERIENCE_IND: CHAR(18)
PHASE4_EXPERIENCE_IND: CHAR(18)
PATIENT_ DATABASE_IND: CHAR(18)
SOFTWARE_PACKAGE_NAME: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
FROM 2220, 2230, 2240 FIG. 22A
TO INV_STAFF_ROLE FIG. 22C
TO INV_WORK_LOCATION FIG. 22C
TO USER_NOTES FIG. 22C
TO HMS_INVESTIGATOR FIG. 22D

FIG. 22B

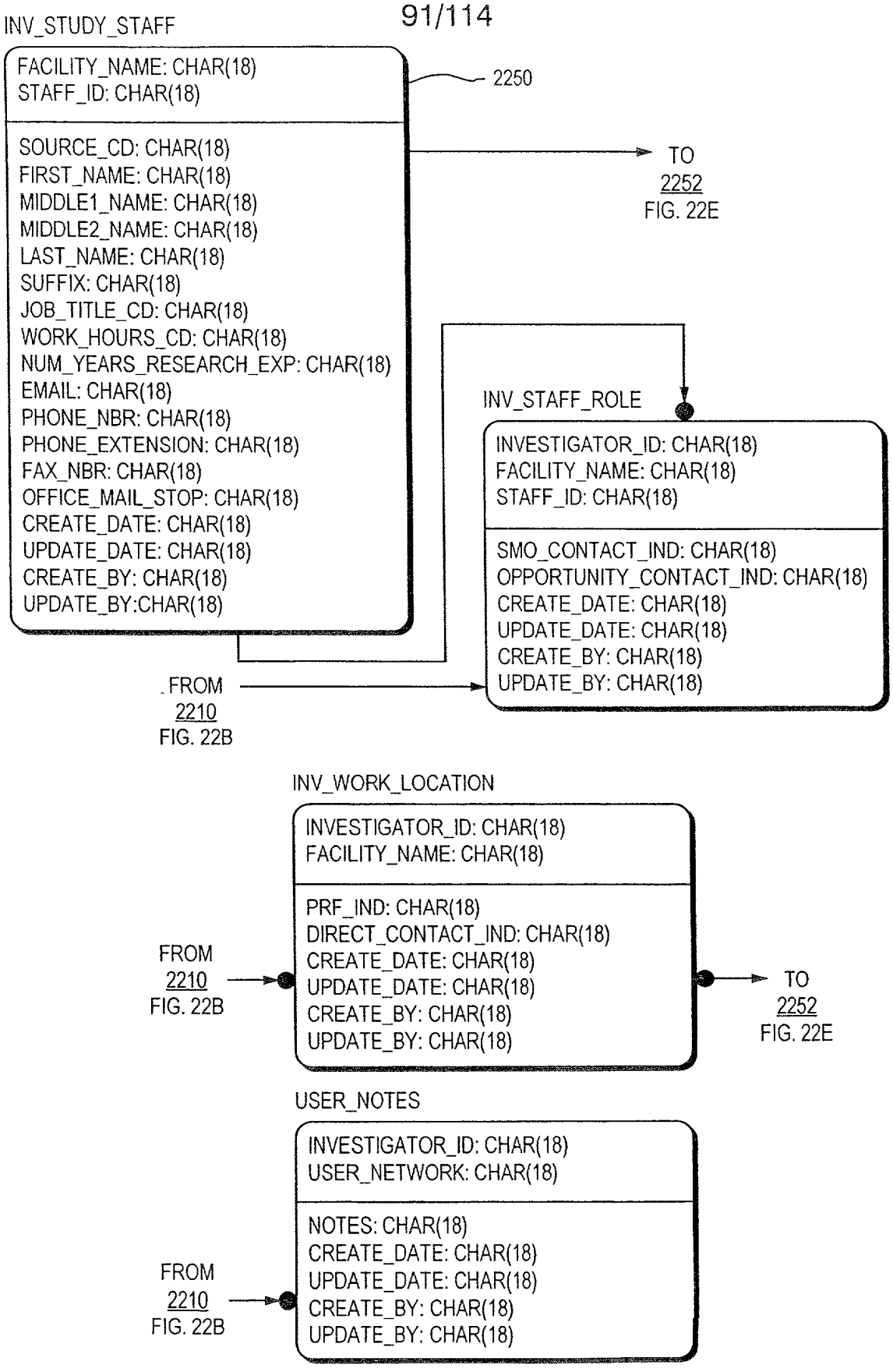

INV_STUDY_STAFF
FACILITY_NAME: CHAR(18)
STAFF_ID: CHAR(18)
2250
SOURCE_CD: CHAR(18)
FIRST_NAME: CHAR(18)
MIDDLE1_NAME: CHAR(18)
MIDDLE2_NAME: CHAR(18)
LAST_NAME: CHAR(18)
SUFFIX: CHAR(18)
JOB_TITLE_CD: CHAR(18)
WORK_HOURS_CD: CHAR(18)
NUM_YEARS_RESEARCH_EXP: CHAR(18)
EMAIL: CHAR(18)
PHONE_NBR: CHAR(18)
PHONE_EXTENSION: CHAR(18)
FAX_NBR: CHAR(18)
OFFICE_MAIL_STOP: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY:CHAR(18)
TO 2252 FIG. 22E
INV_STAFF_ROLE
INVESTIGATOR_ID: CHAR(18)
FACILITY_NAME: CHAR(18)
STAFF_ID: CHAR(18)
SMO_CONTACT_IND: CHAR(18)
OPPORTUNITY_CONTACT_IND: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
FROM 2210 FIG. 22B
INV_WORK_LOCATION
INVESTIGATOR_ID: CHAR(18)
FACILITY_NAME: CHAR(18)
PRF_IND: CHAR(18)
DIRECT_CONTACT_IND: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
FROM 2210 FIG. 22B
TO 2252 FIG. 22E
USER_NOTES
INVESTIGATOR_ID: CHAR(18)
USER_NETWORK: CHAR(18)
NOTES: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
FROM 2210 FIG. 22B

FIG. 22C

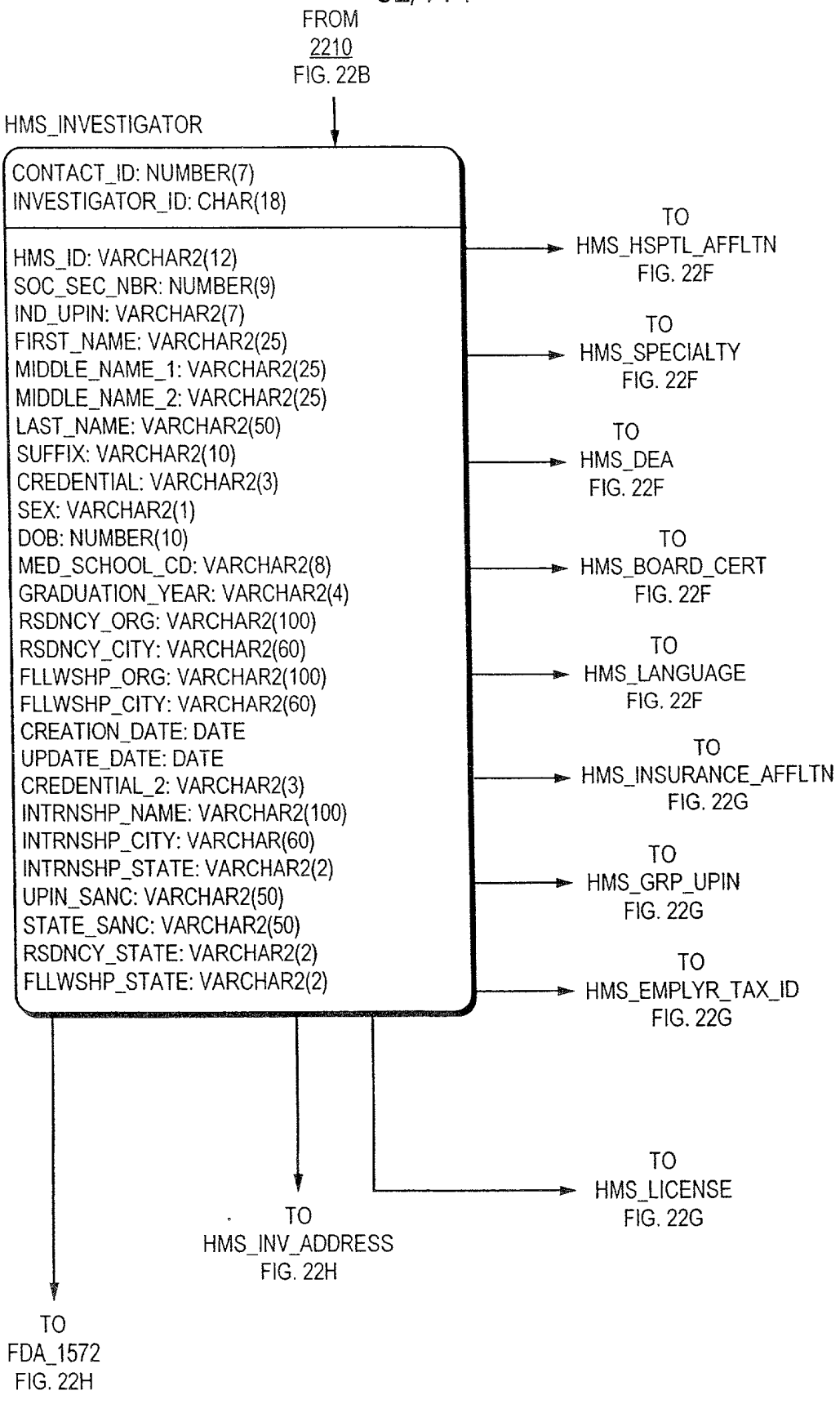

FROM
2210
FIG. 22B
HMS_INVESTIGATOR
CONTACT_ID: NUMBER(7)
INVESTIGATOR_ID: CHAR(18)
HMS_ID: VARCHAR2(12)
SOC_SEC_NBR: NUMBER(9)
IND_UPIN: VARCHAR2(7)
FIRST_NAME: VARCHAR2(25)
MIDDLE_NAME_1: VARCHAR2(25)
MIDDLE_NAME_2: VARCHAR2(25)
LAST_NAME: VARCHAR2(50)
SUFFIX: VARCHAR2(10)
CREDENTIAL: VARCHAR2(3)
SEX: VARCHAR2(1)
DOB: NUMBER(10)
MED_SCHOOL_CD: VARCHAR2(8)
GRADUATION_YEAR: VARCHAR2(4)
RSDNCY_ORG: VARCHAR2(100)
RSDNCY_CITY: VARCHAR2(60)
FLLWSHP_ORG: VARCHAR2(100)
FLLWSHP_CITY: VARCHAR2(60)
CREATION_DATE: DATE
UPDATE_DATE: DATE
CREDENTIAL_2: VARCHAR2(3)
INTRNSHP_NAME: VARCHAR2(100)
INTRNSHP_CITY: VARCHAR(60)
INTRNSHP_STATE: VARCHAR2(2)
UPIN_SANC: VARCHAR2(50)
STATE_SANC: VARCHAR2(50)
RSDNCY_STATE: VARCHAR2(2)
FLLWSHP_STATE: VARCHAR2(2)
TO
HMS_HSPTL_AFFLTN
FIG. 22F
TO
HMS_SPECIALTY
FIG. 22F
TO
HMS_DEA
FIG. 22F
TO
HMS_BOARD_CERT
FIG. 22F
TO
HMS_LANGUAGE
FIG. 22F
TO
HMS_INSURANCE_AFFLTN
FIG. 22G
TO
HMS_GRP_UPIN
FIG. 22G
TO
HMS_EMPLYR_TAX_ID
FIG. 22G
TO
HMS_LICENSE
FIG. 22G
TO
HMS_INV_ADDRESS
FIG. 22H
TO
FDA_1572
FIG. 22H

FIG. 22D

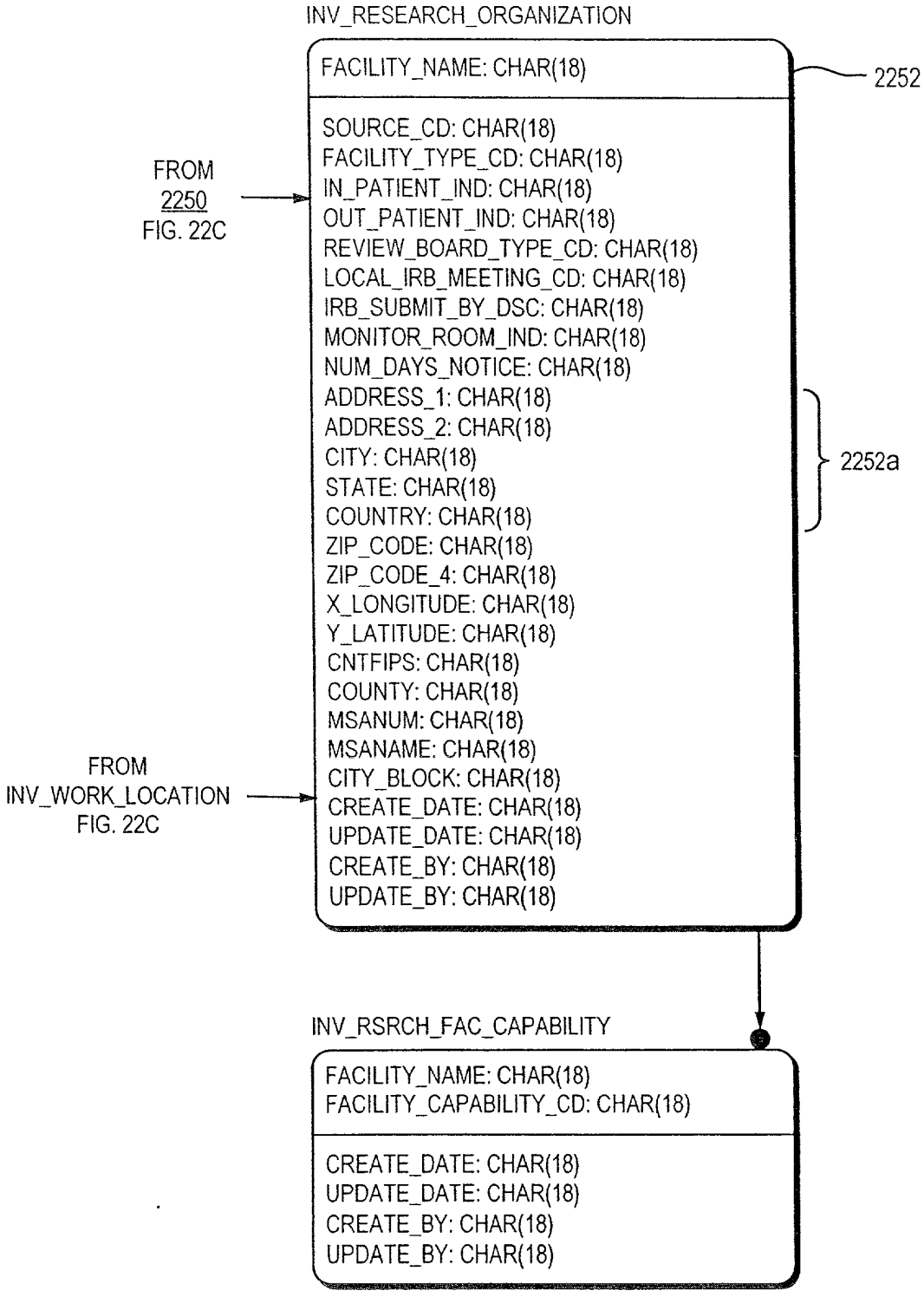

INV_RESEARCH_ORGANIZATION
FACILITY_NAME: CHAR(18)
2252
SOURCE_CD: CHAR(18)
FACILITY_TYPE_CD: CHAR(18)
IN_PATIENT_IND: CHAR(18)
OUT_PATIENT_IND: CHAR(18)
REVIEW_BOARD_TYPE_CD: CHAR(18)
LOCAL_IRB_MEETING_CD: CHAR(18)
IRB_SUBMIT_BY_DSC: CHAR(18)
MONITOR_ROOM_IND: CHAR(18)
NUM_DAYS_NOTICE: CHAR(18)
ADDRESS_1: CHAR(18)
ADDRESS_2: CHAR(18)
CITY: CHAR(18)
STATE: CHAR(18)
COUNTRY: CHAR(18)
ZIP_CODE: CHAR(18)
ZIP_CODE_4: CHAR(18)
X_LONGITUDE: CHAR(18)
Y_LATITUDE: CHAR(18)
CNTFIPS: CHAR(18)
COUNTY: CHAR(18)
MSANUM: CHAR(18)
MSANAME: CHAR(18)
CITY_BLOCK: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
2252a
FROM
2250
FIG. 22C
FROM
INV_WORK_LOCATION
FIG. 22C
INV_RSRCH_FAC_CAPABILITY
FACILITY_NAME: CHAR(18)
FACILITY_CAPABILITY_CD: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)

FIG. 22E

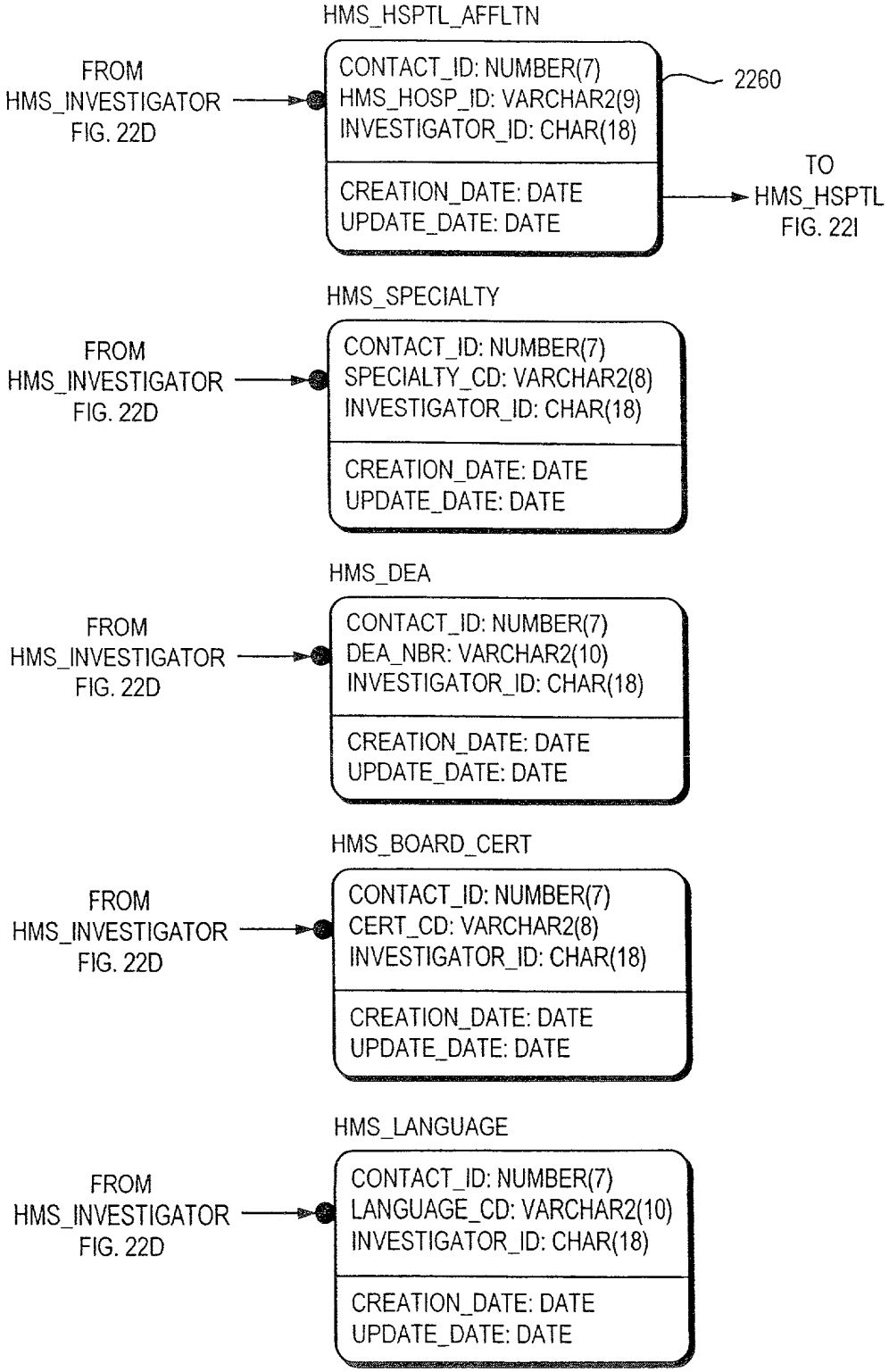

HMS_HSPTL_AFFLTN
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
2260
TO HMS_HSPTL FIG. 22I
HMS_SPECIALTY
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
SPECIALTY_CD: VARCHAR2(8)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_DEA
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
DEA_NBR: VARCHAR2(10)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_BOARD_CERT
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
CERT_CD: VARCHAR2(8)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_LANGUAGE
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
LANGUAGE_CD: VARCHAR2(10)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE

FIG. 22F

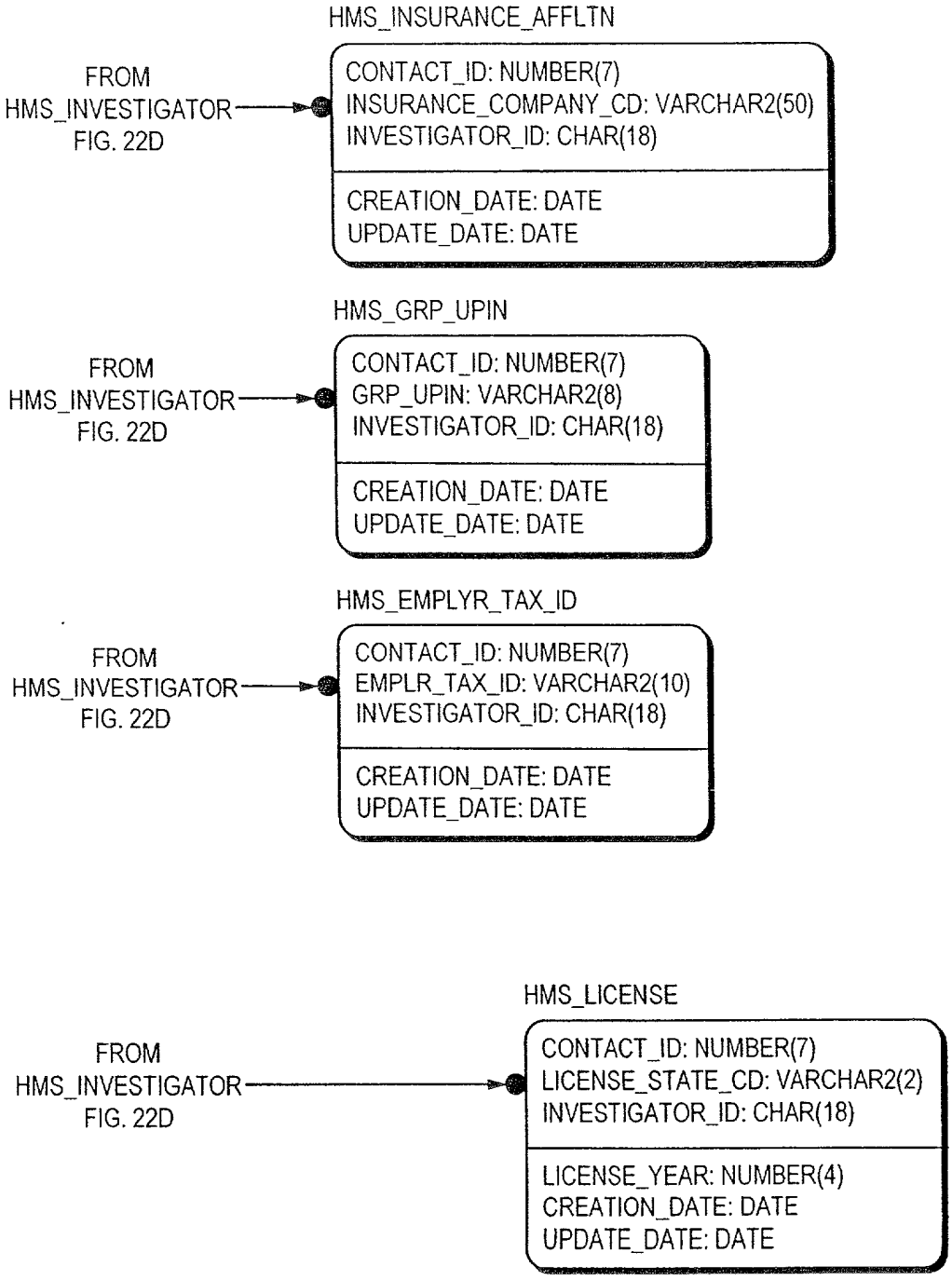

HMS_INSURANCE_AFFLTN
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
INSURANCE_COMPANY_CD: VARCHAR2(50)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_GRP_UPIN
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
GRP_UPIN: VARCHAR2(8)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_EMPLYR_TAX_ID
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
EMPLR_TAX_ID: VARCHAR2(10)
INVESTIGATOR_ID: CHAR(18)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_LICENSE
FROM HMS_INVESTIGATOR FIG. 22D
CONTACT_ID: NUMBER(7)
LICENSE_STATE_CD: VARCHAR2(2)
INVESTIGATOR_ID: CHAR(18)
LICENSE_YEAR: NUMBER(4)
CREATION_DATE: DATE
UPDATE_DATE: DATE

FIG. 22G

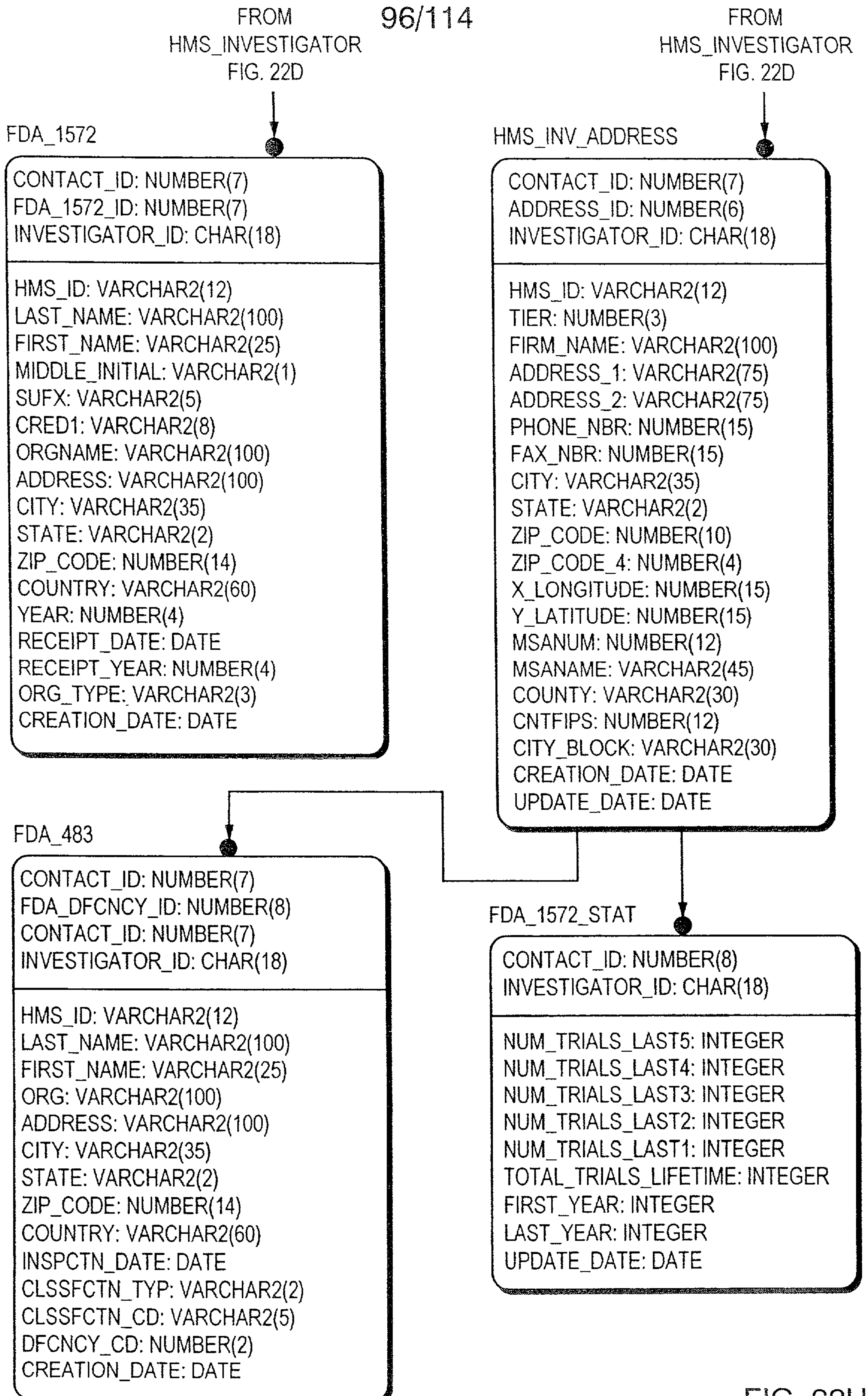

FROM
HMS_INVESTIGATOR
FIG. 22D
FROM
HMS_INVESTIGATOR
FIG. 22D
FDA_1572
CONTACT_ID: NUMBER(7)
FDA_1572_ID: NUMBER(7)
INVESTIGATOR_ID: CHAR(18)
HMS_ID: VARCHAR2(12)
LAST_NAME: VARCHAR2(100)
FIRST_NAME: VARCHAR2(25)
MIDDLE_INITIAL: VARCHAR2(1)
SUFX: VARCHAR2(5)
CRED1: VARCHAR2(8)
ORGNAME: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP_CODE: NUMBER(14)
COUNTRY: VARCHAR2(60)
YEAR: NUMBER(4)
RECEIPT_DATE: DATE
RECEIPT_YEAR: NUMBER(4)
ORG_TYPE: VARCHAR2(3)
CREATION_DATE: DATE
HMS_INV_ADDRESS
CONTACT_ID: NUMBER(7)
ADDRESS_ID: NUMBER(6)
INVESTIGATOR_ID: CHAR(18)
HMS_ID: VARCHAR2(12)
TIER: NUMBER(3)
FIRM_NAME: VARCHAR2(100)
ADDRESS_1: VARCHAR2(75)
ADDRESS_2: VARCHAR2(75)
PHONE_NBR: NUMBER(15)
FAX_NBR: NUMBER(15)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP_CODE: NUMBER(10)
ZIP_CODE_4: NUMBER(4)
X_LONGITUDE: NUMBER(15)
Y_LATITUDE: NUMBER(15)
MSANUM: NUMBER(12)
MSANAME: VARCHAR2(45)
COUNTY: VARCHAR2(30)
CNTFIPS: NUMBER(12)
CITY_BLOCK: VARCHAR2(30)
CREATION_DATE: DATE
UPDATE_DATE: DATE
FDA_483
CONTACT_ID: NUMBER(7)
FDA_DFCNCY_ID: NUMBER(8)
CONTACT_ID: NUMBER(7)
INVESTIGATOR_ID: CHAR(18)
HMS_ID: VARCHAR2(12)
LAST_NAME: VARCHAR2(100)
FIRST_NAME: VARCHAR2(25)
ORG: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP_CODE: NUMBER(14)
COUNTRY: VARCHAR2(60)
INSPCTN_DATE: DATE
CLSSFCTN_TYP: VARCHAR2(2)
CLSSFCTN_CD: VARCHAR2(5)
DFCNCY_CD: NUMBER(2)
CREATION_DATE: DATE
FDA_1572_STAT
CONTACT_ID: NUMBER(8)
INVESTIGATOR_ID: CHAR(18)
NUM_TRIALS_LAST5: INTEGER
NUM_TRIALS_LAST4: INTEGER
NUM_TRIALS_LAST3: INTEGER
NUM_TRIALS_LAST2: INTEGER
NUM_TRIALS_LAST1: INTEGER
TOTAL_TRIALS_LIFETIME: INTEGER
FIRST_YEAR: INTEGER
LAST_YEAR: INTEGER
UPDATE_DATE: DATE

FIG. 22H

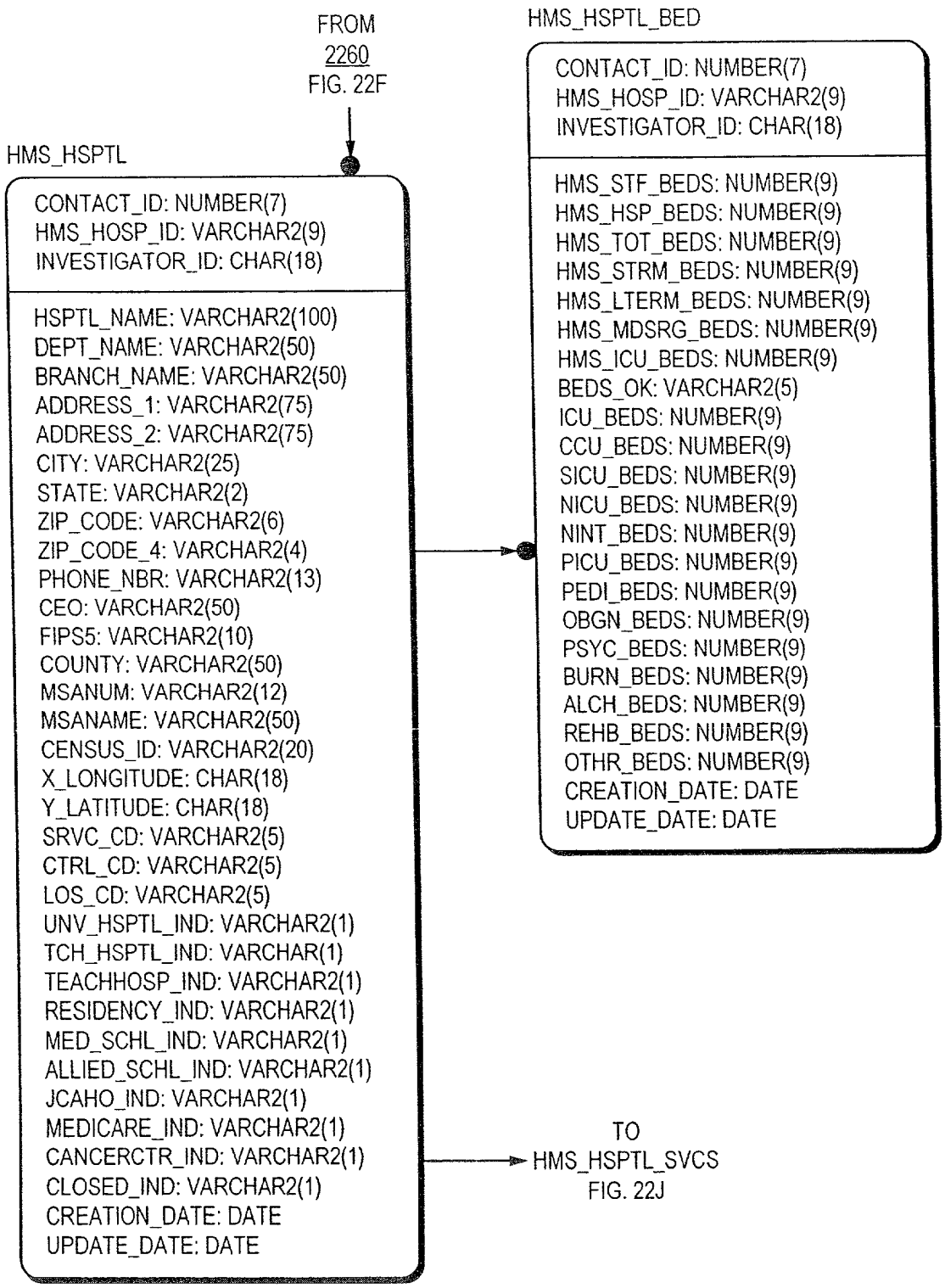

FROM
2260
FIG. 22F
HMS_HSPTL
CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR_ID: CHAR(18)
HSPTL_NAME: VARCHAR2(100)
DEPT_NAME: VARCHAR2(50)
BRANCH_NAME: VARCHAR2(50)
ADDRESS_1: VARCHAR2(75)
ADDRESS_2: VARCHAR2(75)
CITY: VARCHAR2(25)
STATE: VARCHAR2(2)
ZIP_CODE: VARCHAR2(6)
ZIP_CODE_4: VARCHAR2(4)
PHONE_NBR: VARCHAR2(13)
CEO: VARCHAR2(50)
FIPS5: VARCHAR2(10)
COUNTY: VARCHAR2(50)
MSANUM: VARCHAR2(12)
MSANAME: VARCHAR2(50)
CENSUS_ID: VARCHAR2(20)
X_LONGITUDE: CHAR(18)
Y_LATITUDE: CHAR(18)
SRVC_CD: VARCHAR2(5)
CTRL_CD: VARCHAR2(5)
LOS_CD: VARCHAR2(5)
UNV_HSPTL_IND: VARCHAR2(1)
TCH_HSPTL_IND: VARCHAR(1)
TEACHHOSP_IND: VARCHAR2(1)
RESIDENCY_IND: VARCHAR2(1)
MED_SCHL_IND: VARCHAR2(1)
ALLIED_SCHL_IND: VARCHAR2(1)
JCAHO_IND: VARCHAR2(1)
MEDICARE_IND: VARCHAR2(1)
CANCERCTR_IND: VARCHAR2(1)
CLOSED_IND: VARCHAR2(1)
CREATION_DATE: DATE
UPDATE_DATE: DATE
HMS_HSPTL_BED
CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR_ID: CHAR(18)
HMS_STF_BEDS: NUMBER(9)
HMS_HSP_BEDS: NUMBER(9)
HMS_TOT_BEDS: NUMBER(9)
HMS_STRM_BEDS: NUMBER(9)
HMS_LTERM_BEDS: NUMBER(9)
HMS_MDSRG_BEDS: NUMBER(9)
HMS_ICU_BEDS: NUMBER(9)
BEDS_OK: VARCHAR2(5)
ICU_BEDS: NUMBER(9)
CCU_BEDS: NUMBER(9)
SICU_BEDS: NUMBER(9)
NICU_BEDS: NUMBER(9)
NINT_BEDS: NUMBER(9)
PICU_BEDS: NUMBER(9)
PEDI_BEDS: NUMBER(9)
OBGN_BEDS: NUMBER(9)
PSYC_BEDS: NUMBER(9)
BURN_BEDS: NUMBER(9)
ALCH_BEDS: NUMBER(9)
REHB_BEDS: NUMBER(9)
OTHR_BEDS: NUMBER(9)
CREATION_DATE: DATE
UPDATE_DATE: DATE
TO
HMS_HSPTL_SVCS
FIG. 22J

FIG. 22I

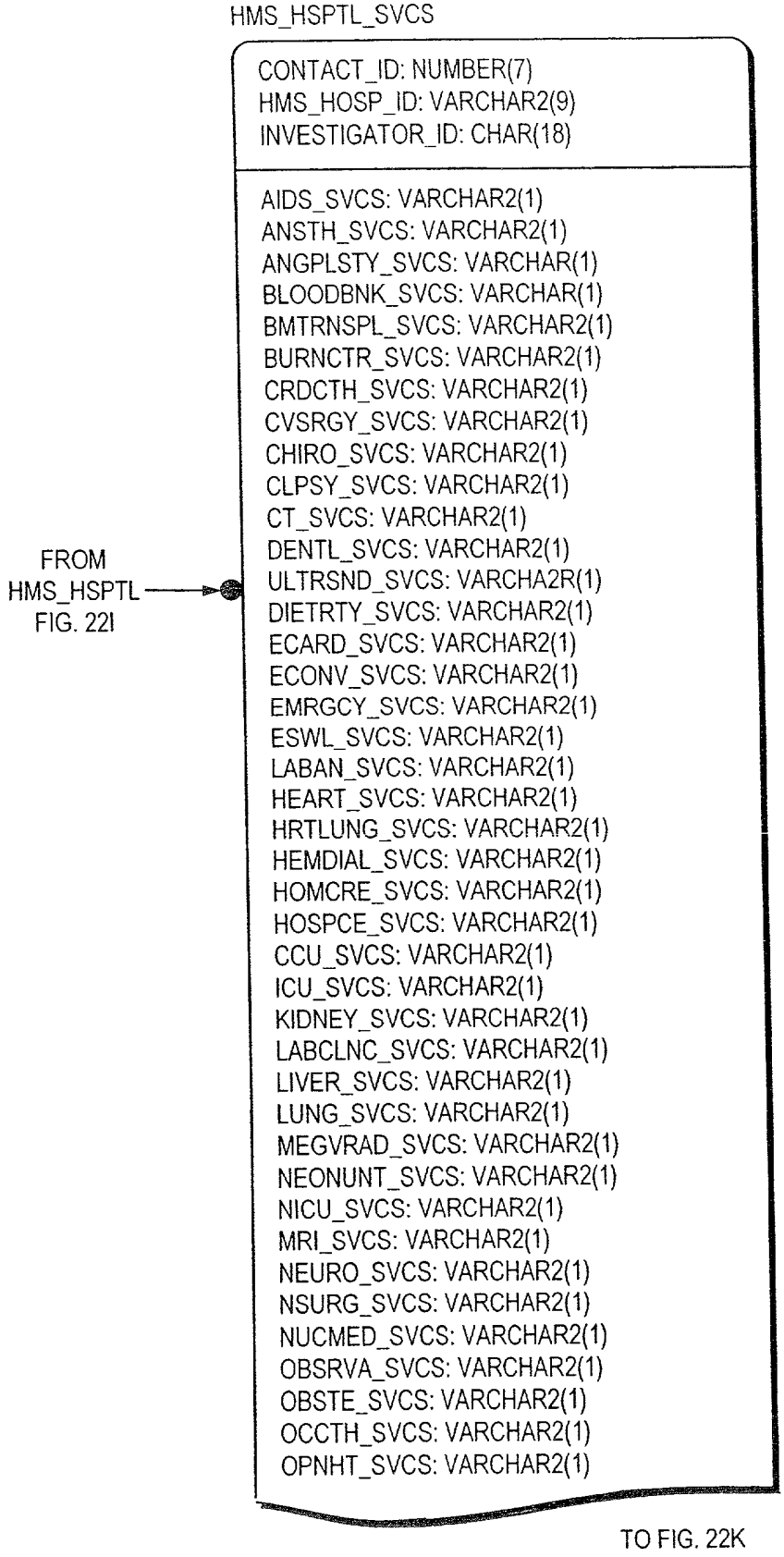

HMS_HSPTL_SVCS
CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR_ID: CHAR(18)
AIDS_SVCS: VARCHAR2(1)
ANSTH_SVCS: VARCHAR2(1)
ANGPLSTY_SVCS: VARCHAR(1)
BLOODBNK_SVCS: VARCHAR(1)
BMTRNSPL_SVCS: VARCHAR2(1)
BURNCTR_SVCS: VARCHAR2(1)
CRDCTH_SVCS: VARCHAR2(1)
CVSRGY_SVCS: VARCHAR2(1)
CHIRO_SVCS: VARCHAR2(1)
CLPSY_SVCS: VARCHAR2(1)
CT_SVCS: VARCHAR2(1)
DENTL_SVCS: VARCHAR2(1)
ULTRSND_SVCS: VARCHA2R(1)
DIETRTY_SVCS: VARCHAR2(1)
ECARD_SVCS: VARCHAR2(1)
ECONV_SVCS: VARCHAR2(1)
EMRGCY_SVCS: VARCHAR2(1)
ESWL_SVCS: VARCHAR2(1)
LABAN_SVCS: VARCHAR2(1)
HEART_SVCS: VARCHAR2(1)
HRTLUNG_SVCS: VARCHAR2(1)
HEMDIAL_SVCS: VARCHAR2(1)
HOMCRE_SVCS: VARCHAR2(1)
HOSPCE_SVCS: VARCHAR2(1)
CCU_SVCS: VARCHAR2(1)
ICU_SVCS: VARCHAR2(1)
KIDNEY_SVCS: VARCHAR2(1)
LABCLNC_SVCS: VARCHAR2(1)
LIVER_SVCS: VARCHAR2(1)
LUNG_SVCS: VARCHAR2(1)
MEGVRAD_SVCS: VARCHAR2(1)
NEONUNT_SVCS: VARCHAR2(1)
NICU_SVCS: VARCHAR2(1)
MRI_SVCS: VARCHAR2(1)
NEURO_SVCS: VARCHAR2(1)
NSURG_SVCS: VARCHAR2(1)
NUCMED_SVCS: VARCHAR2(1)
OBSRVA_SVCS: VARCHAR2(1)
OBSTE_SVCS: VARCHAR2(1)
OCCTH_SVCS: VARCHAR2(1)
OPNHT_SVCS: VARCHAR2(1)
FROM HMS_HSPTL FIG. 22I
TO FIG. 22K

FIG. 22J

HMS_HSPTL_SVCS (CONT'D)

FROM FIG. 22J

OPTOM_SVCS: VARCHAR2(1)
ORGBANK_SVCS: VARCHAR2(1)
ORGAN_SVCS: VARCHAR2(1)
OUTPAT_SVCS: VARCHAR2(1)
OUTSRG_SVCS: VARCHAR2(1)
PANCR_SVCS: VARCHAR2(1)
PEDIAT_SVCS: VARCHAR2(1)
PHARM_SVCS: VARCHAR2(1)
PHYTH_SVCS: VARCHAR2(1)
PSTOP_SVCS: VARCHAR2(1)
PSYED_SVCS: VARCHAR2(1)
PULMON_SVCS: VARCHAR2(1)
RADIM_SVCS: VARCHAR2(1)
RECTH_SVCS: VARCHAR2(1)
REHAB_SVCS: VARCHAR2(1)
RESPIR_SVCS: VARCHAR2(1)
SELFCARE_SVCS: VARCHAR2(1)
SKNLT_SVCS: VARCHAR2(1)
SOCSVC_SVCS: VARCHAR2(1)
SPEECH_SVCS: VARCHAR2(1)
THERD_SVCS: VARCHAR2(1)
TRAUMA_SVCS: VARCHAR2(1)
XRADT_SVCS: VARCHAR2(1)
CREATION_DATE: DATE
UPDATE_DATE: DATE

FIG. 22K

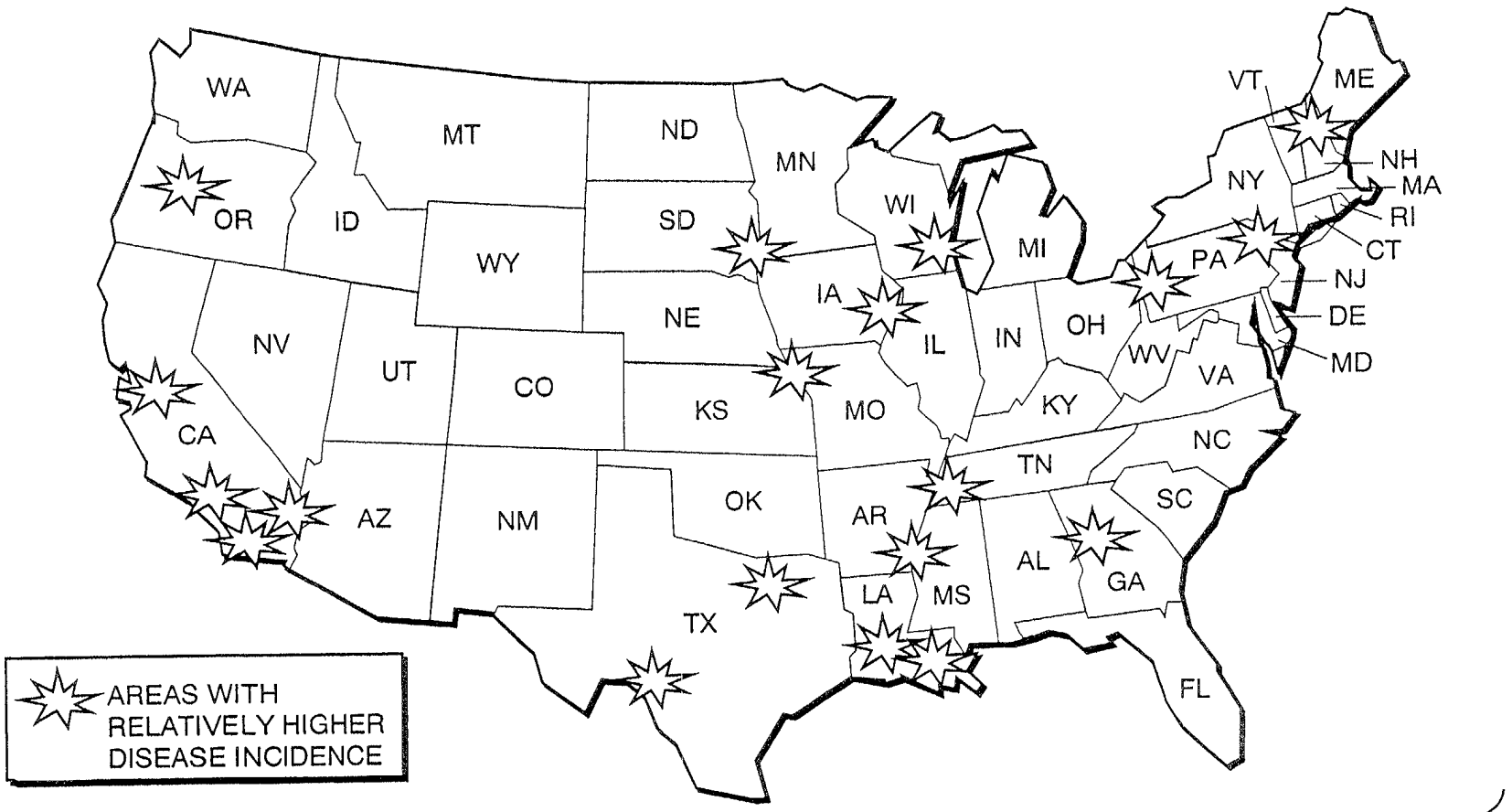

WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MS
MI
IN
KY
TN
AL
OH
WV
GA
FL
SC
NC
VA
PA
NY
VT
ME
NH
MA
RI
CT
NJ
DE
MD
AREAS WITH RELATIVELY HIGHER DISEASE INCIDENCE

FIG. 22L

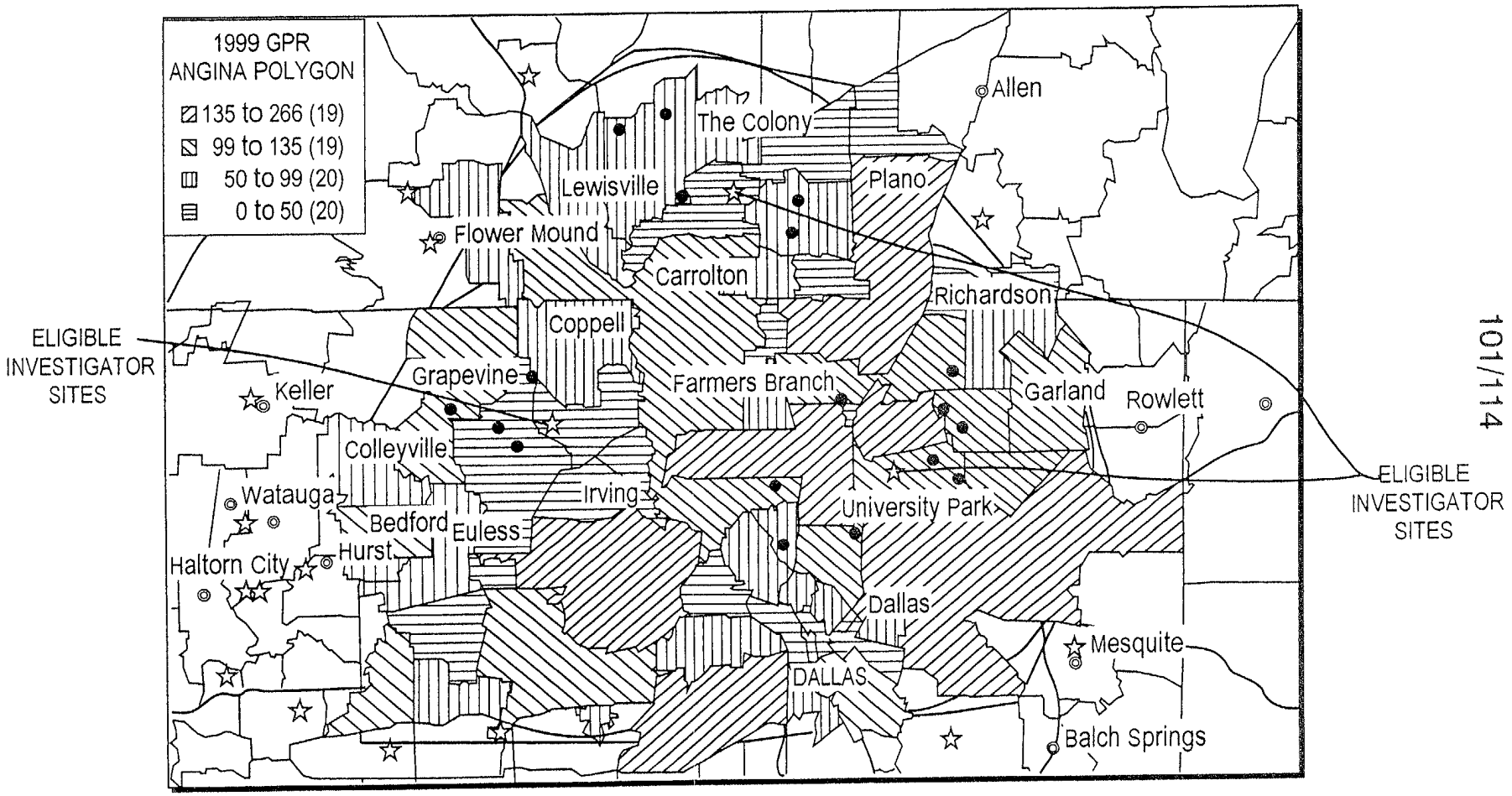

1999 GPR
ANGINA POLYGON
135 to 266 (19)
99 to 135 (19)
50 to 99 (20)
0 to 50 (20)
ELIGIBLE
INVESTIGATOR
SITES
ELIGIBLE
INVESTIGATOR
SITES
Allen
The Colony
Plano
Lewisville
Flower Mound
Carrolton
Richardson
Coppell
Grapevine
Keller
Farmers Branch
Garland
Rowlett
Colleyville
Watauga
Irving
University Park
Bedford
Euless
Hurst
Haltorn City
Dallas
Mesquite
DALLAS
Balch Springs

FIG. 22M

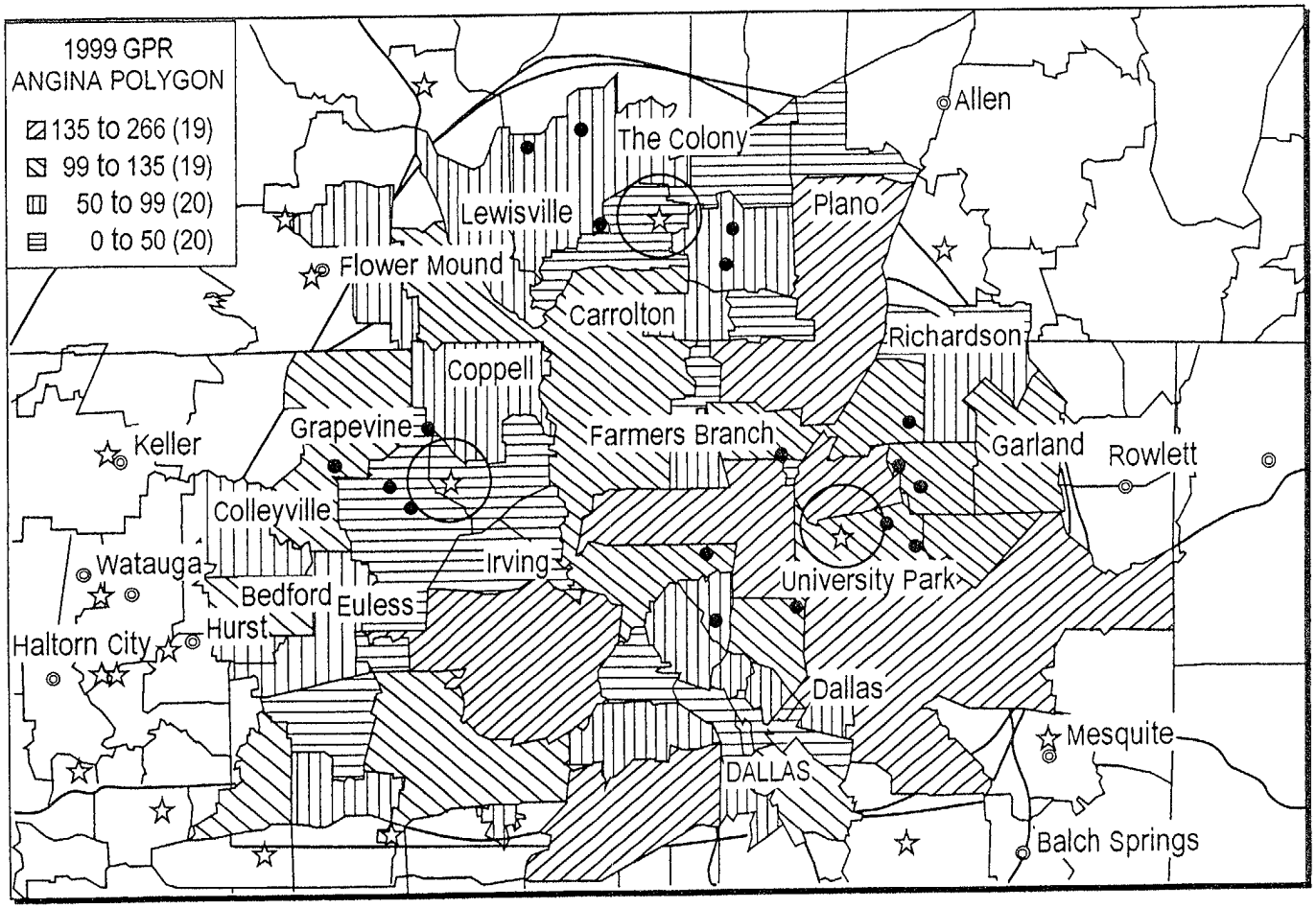

1999 GPR
ANGINA POLYGON
135 to 266 (19)
99 to 135 (19)
50 to 99 (20)
0 to 50 (20)
Allen
The Colony
Plano
Lewisville
Flower Mound
Carrolton
Richardson
Coppell
Grapevine
Keller
Farmers Branch
Garland
Rowlett
Colleyville
Watauga
Irving
University Park
Bedford
Euless
Hurst
Haltorn City
Dallas
Mesquite
DALLAS
Balch Springs

FIG. 22N

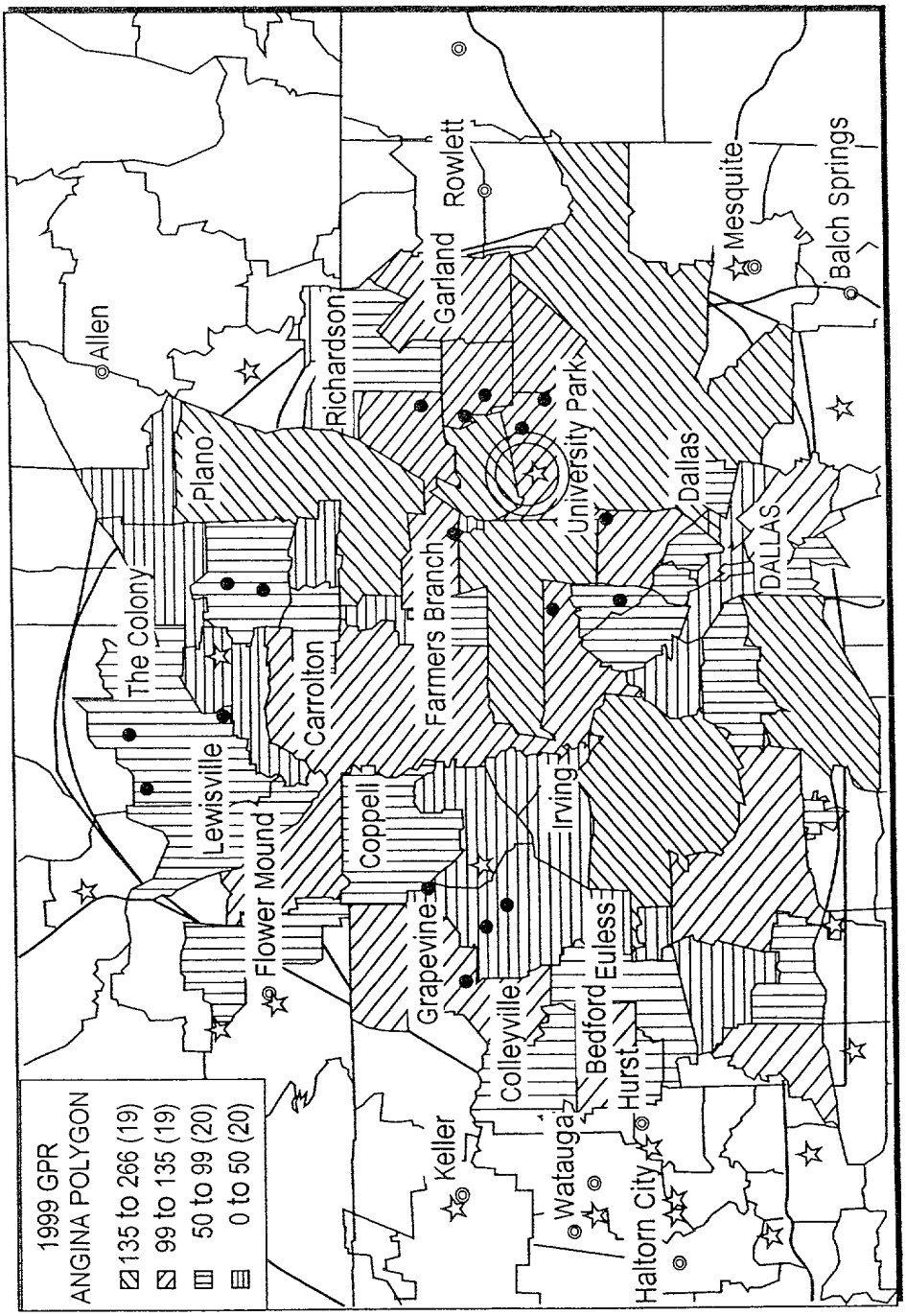

1999 GPR
ANGINA POLYGON
135 to 266 (19)
99 to 135 (19)
50 to 99 (20)
0 to 50 (20)
Allen
Plano
Richardson
Garland
Rowlett
Mesquite
Balch Springs
The Colony
Carrollton
Farmers Branch
University Park
Dallas
DALLAS
Lewisville
Flower Mound
Coppell
Irving
Grapevine
Colleyville
Bedford
Euless
Hurst
Keller
Watauga
Haltorn City

FIG. 22O

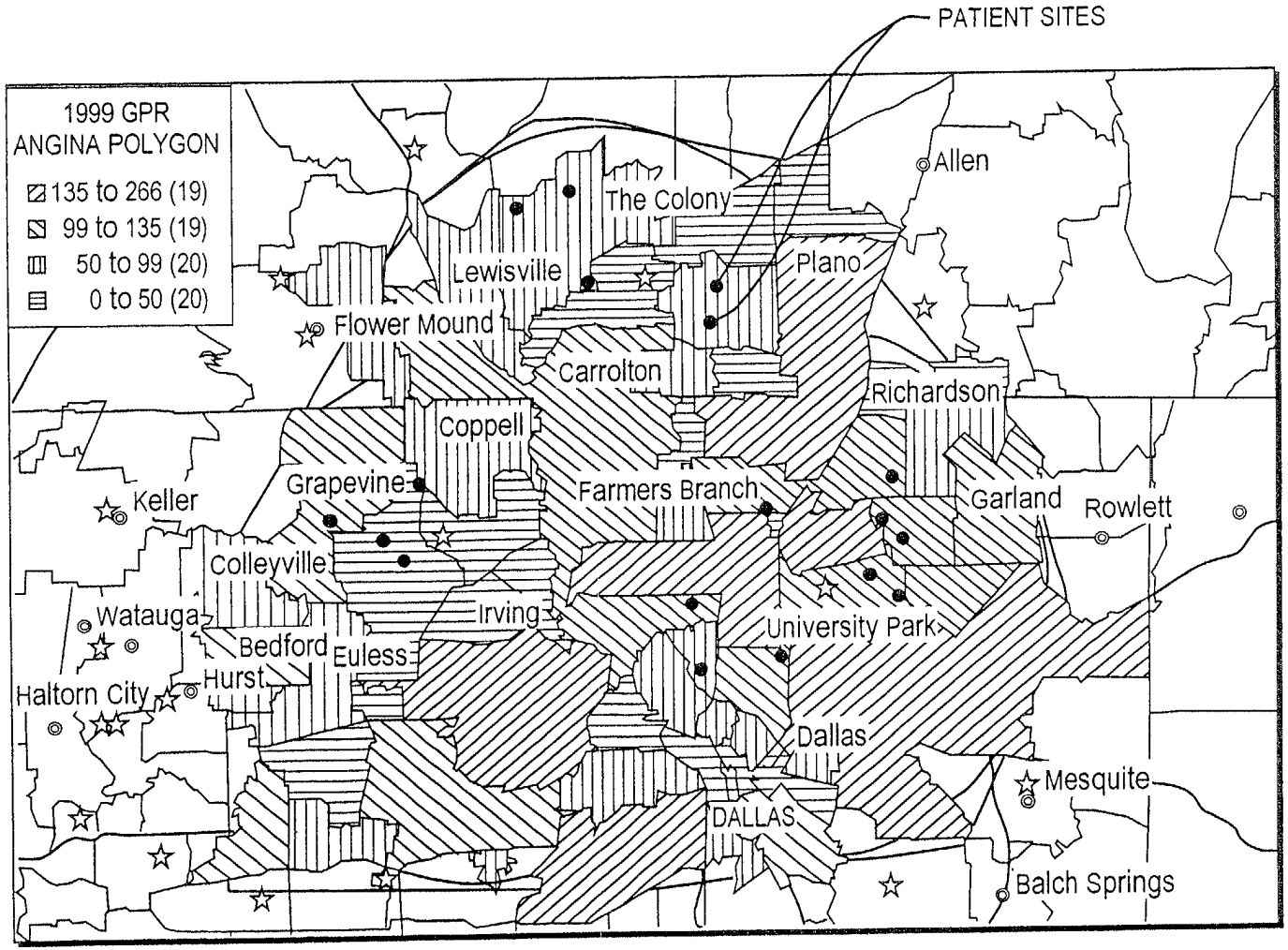
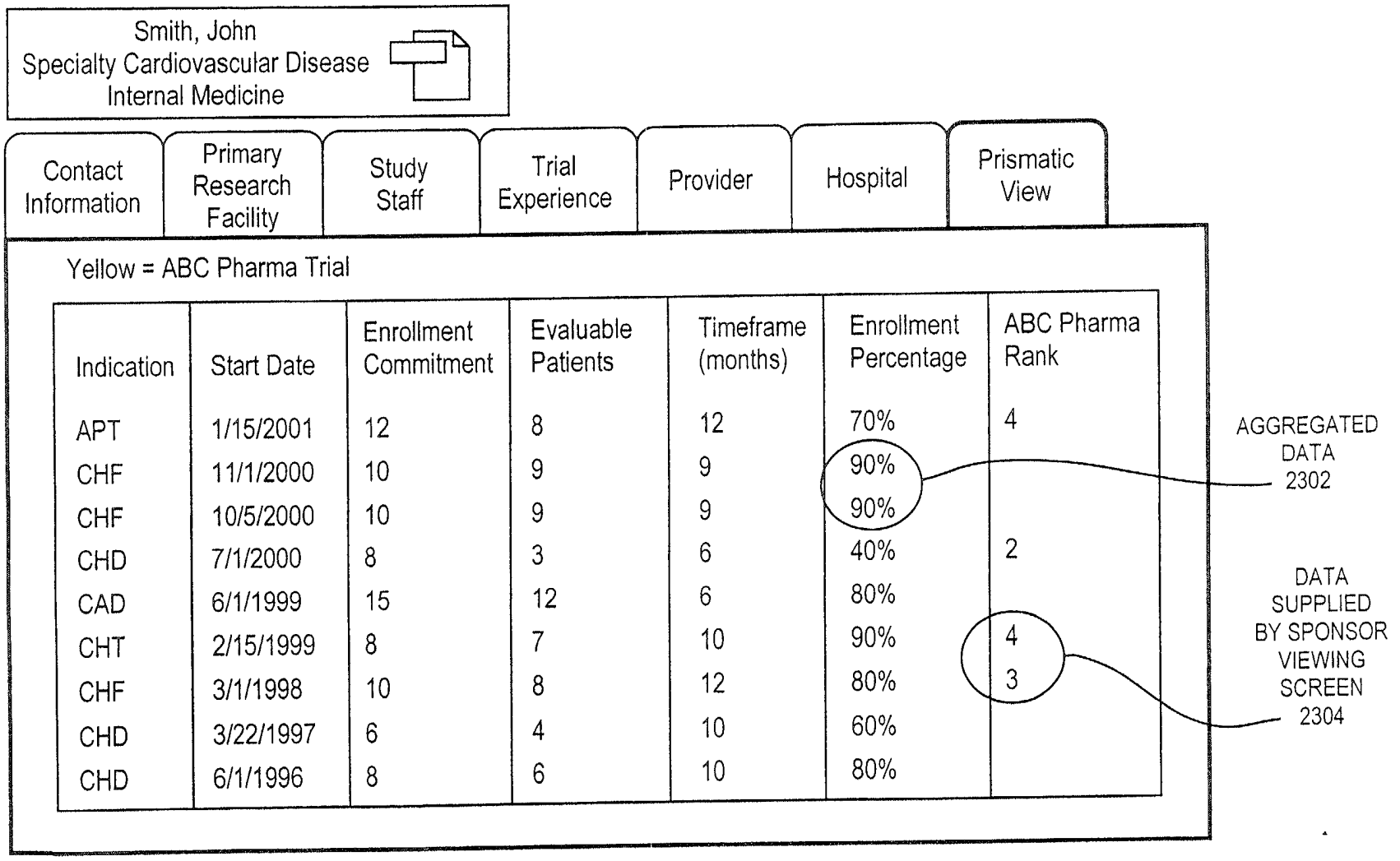

PATIENT SITES
1999 GPR
ANGINA POLYGON
135 to 266 (19)
99 to 135 (19)
50 to 99 (20)
0 to 50 (20)
Allen
The Colony
Plano
Lewisville
Flower Mound
Carrolton
Richardson
Coppell
Grapevine
Farmers Branch
Garland
Rowlett
Keller
Colleyville
Watauga
Irving
University Park
Bedford
Euless
Hurst
Haltorn City
Dallas
Mesquite
DALLAS
Balch Springs

FIG. 22P



105/114

FIG. 23

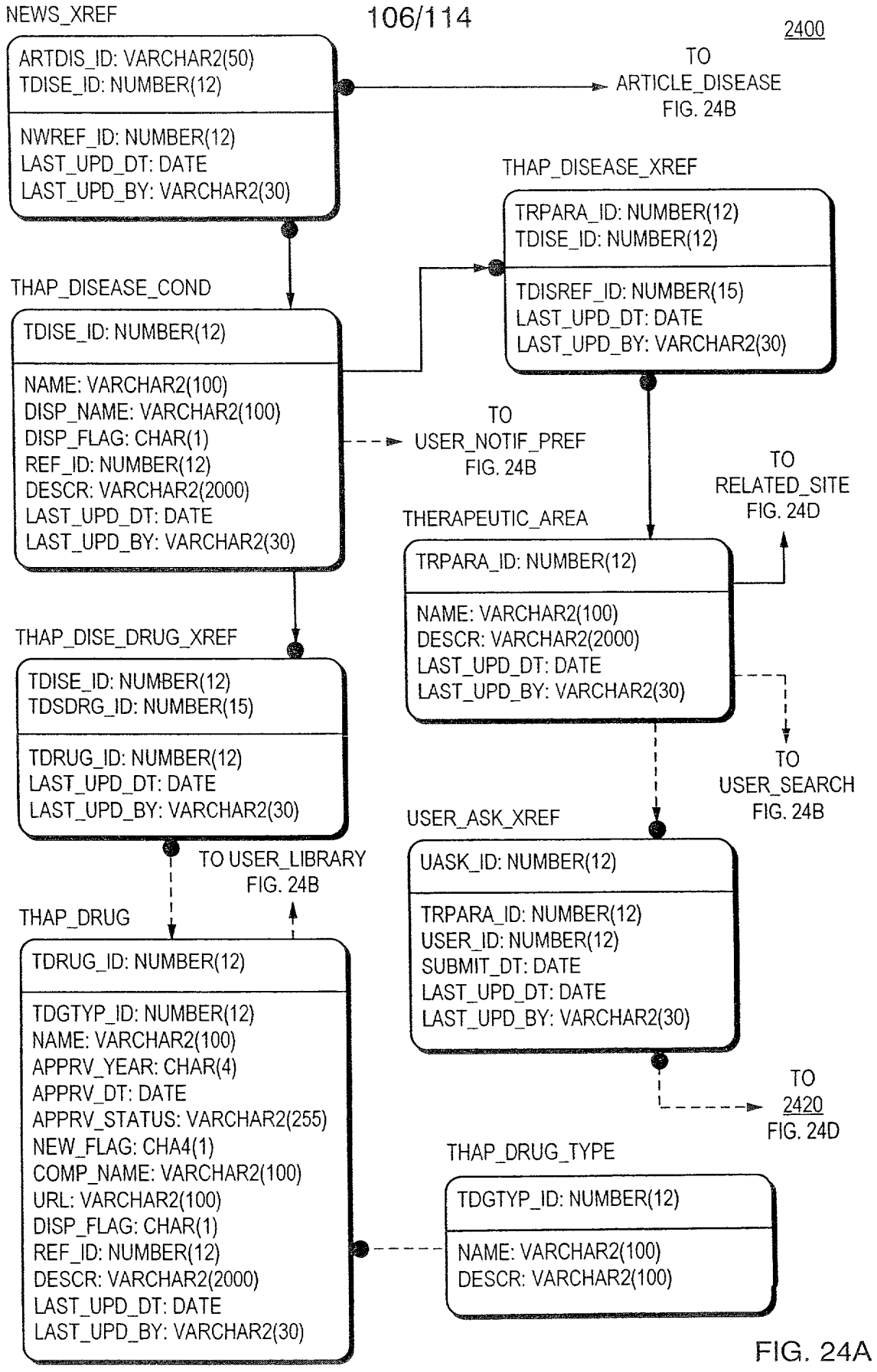

2400
NEWS_XREF
ARTDIS_ID: VARCHAR2(50)
TDISE_ID: NUMBER(12)
NWREF_ID: NUMBER(12)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO ARTICLE_DISEASE FIG. 24B
THAP_DISEASE_XREF
TRPARA_ID: NUMBER(12)
TDISE_ID: NUMBER(12)
TDISREF_ID: NUMBER(15)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
THAP_DISEASE_COND
TDISE_ID: NUMBER(12)
NAME: VARCHAR2(100)
DISP_NAME: VARCHAR2(100)
DISP_FLAG: CHAR(1)
REF_ID: NUMBER(12)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO USER_NOTIF_PREF FIG. 24B
TO RELATED_SITE FIG. 24D
THERAPEUTIC_AREA
TRPARA_ID: NUMBER(12)
NAME: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO USER_SEARCH FIG. 24B
THAP_DISE_DRUG_XREF
TDISE_ID: NUMBER(12)
TDSDRG_ID: NUMBER(15)
TDRUG_ID: NUMBER(12)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO USER_LIBRARY FIG. 24B
USER_ASK_XREF
UASK_ID: NUMBER(12)
TRPARA_ID: NUMBER(12)
USER_ID: NUMBER(12)
SUBMIT_DT: DATE
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO 2420 FIG. 24D
THAP_DRUG
TDRUG_ID: NUMBER(12)
TDGTYP_ID: NUMBER(12)
NAME: VARCHAR2(100)
APPRV_YEAR: CHAR(4)
APPRV_DT: DATE
APPRV_STATUS: VARCHAR2(255)
NEW_FLAG: CHA4(1)
COMP_NAME: VARCHAR2(100)
URL: VARCHAR2(100)
DISP_FLAG: CHAR(1)
REF_ID: NUMBER(12)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
THAP_DRUG_TYPE
TDGTYP_ID: NUMBER(12)
NAME: VARCHAR2(100)
DESCR: VARCHAR2(100)

FIG. 24A

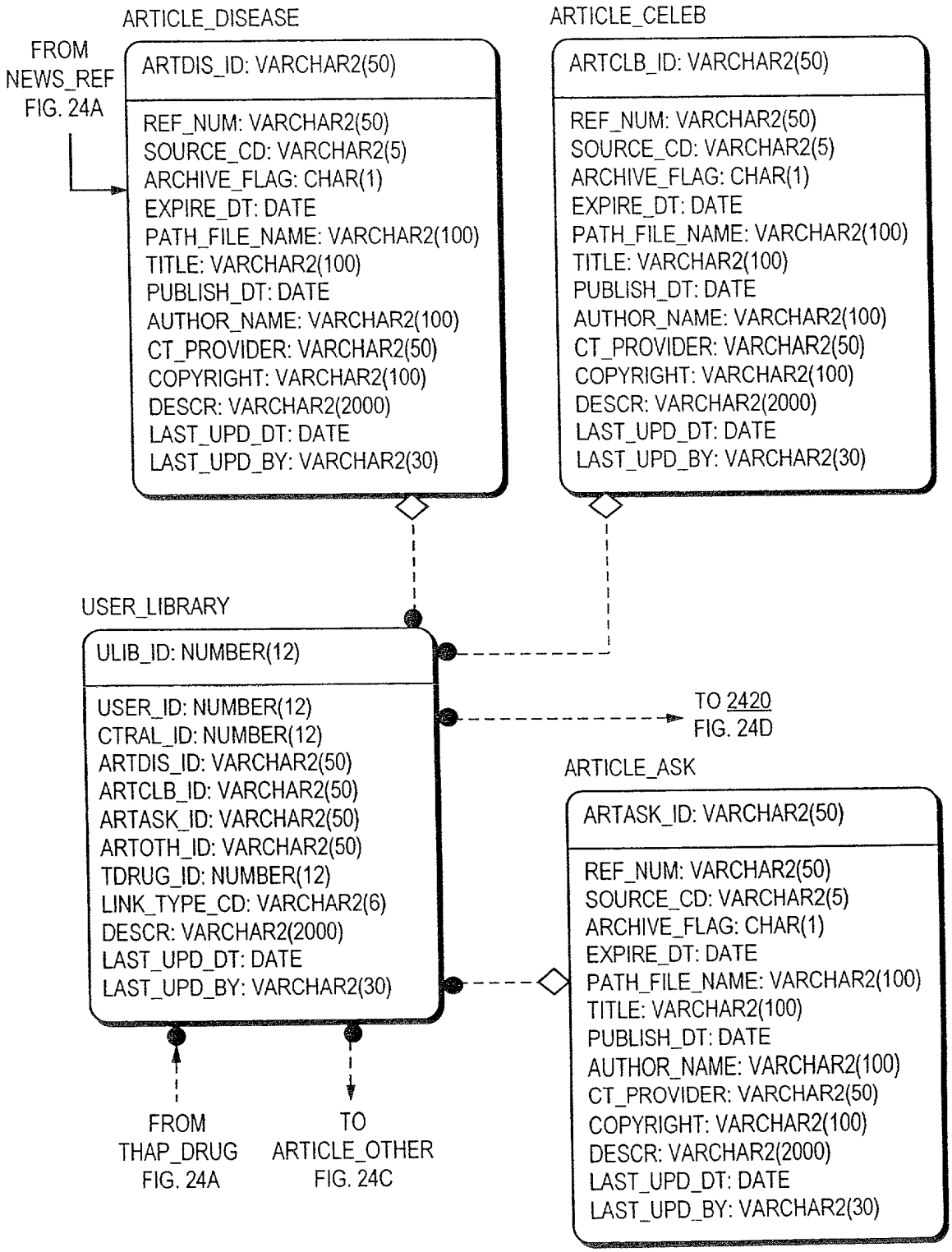

ARTICLE_DISEASE
FROM NEWS_REF FIG. 24A
ARTDIS_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ARTICLE_CELEB
ARTCLB_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
USER_LIBRARY
ULIB_ID: NUMBER(12)
USER_ID: NUMBER(12)
CTRAL_ID: NUMBER(12)
ARTDIS_ID: VARCHAR2(50)
ARTCLB_ID: VARCHAR2(50)
ARTASK_ID: VARCHAR2(50)
ARTOTH_ID: VARCHAR2(50)
TDRUG_ID: NUMBER(12)
LINK_TYPE_CD: VARCHAR2(6)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO 2420 FIG. 24D
ARTICLE_ASK
ARTASK_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
FROM THAP_DRUG FIG. 24A
TO ARTICLE_OTHER FIG. 24C

FIG. 24B

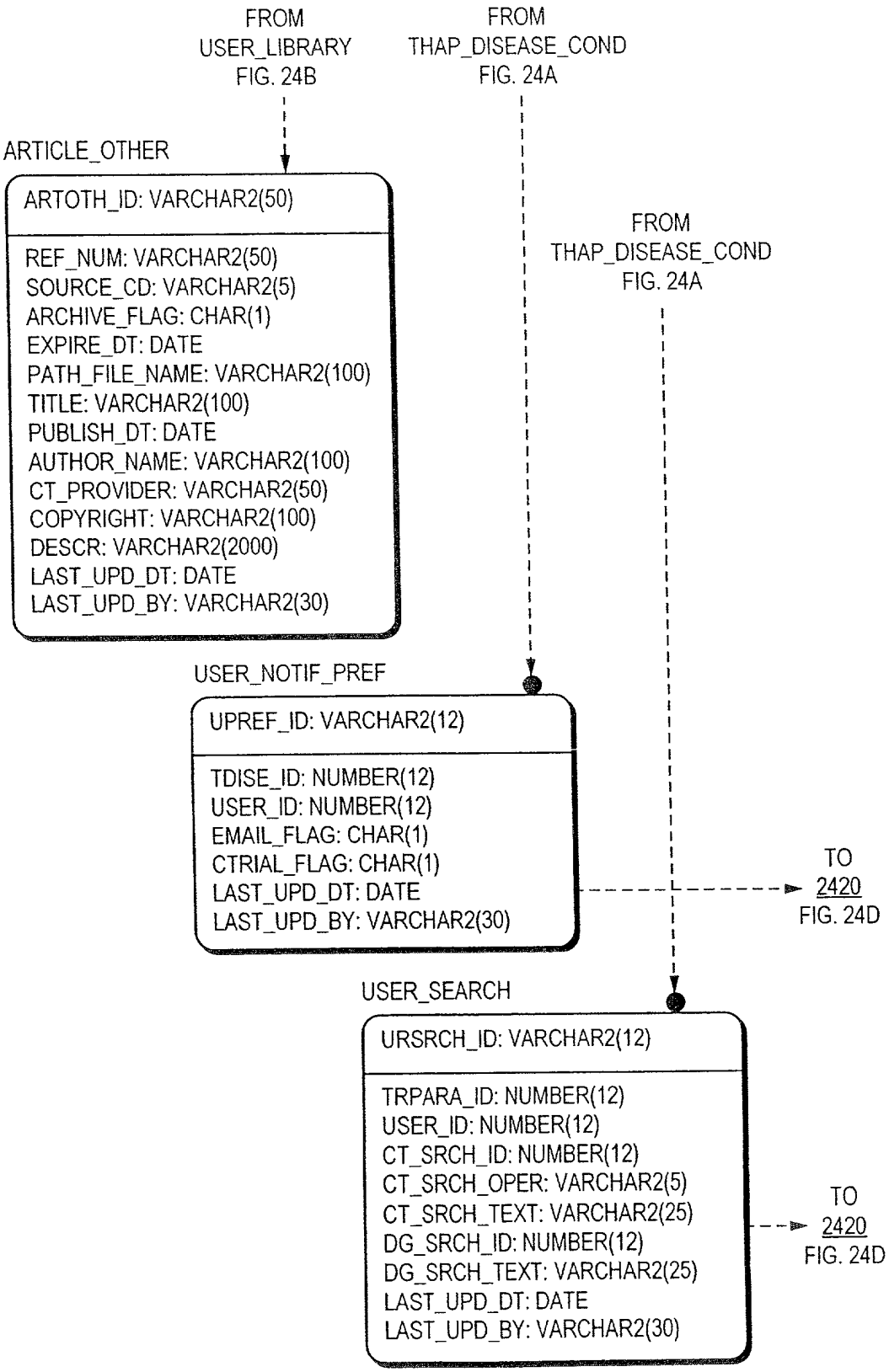

FROM
USER_LIBRARY
FIG. 24B
FROM
THAP_DISEASE_COND
FIG. 24A
ARTICLE_OTHER
ARTOTH_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
FROM
THAP_DISEASE_COND
FIG. 24A
USER_NOTIF_PREF
UPREF_ID: VARCHAR2(12)
TDISE_ID: NUMBER(12)
USER_ID: NUMBER(12)
EMAIL_FLAG: CHAR(1)
CTRIAL_FLAG: CHAR(1)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO
2420
FIG. 24D
USER_SEARCH
URSRCH_ID: VARCHAR2(12)
TRPARA_ID: NUMBER(12)
USER_ID: NUMBER(12)
CT_SRCH_ID: NUMBER(12)
CT_SRCH_OPER: VARCHAR2(5)
CT_SRCH_TEXT: VARCHAR2(25)
DG_SRCH_ID: NUMBER(12)
DG_SRCH_TEXT: VARCHAR2(25)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO
2420
FIG. 24D

FIG. 24C

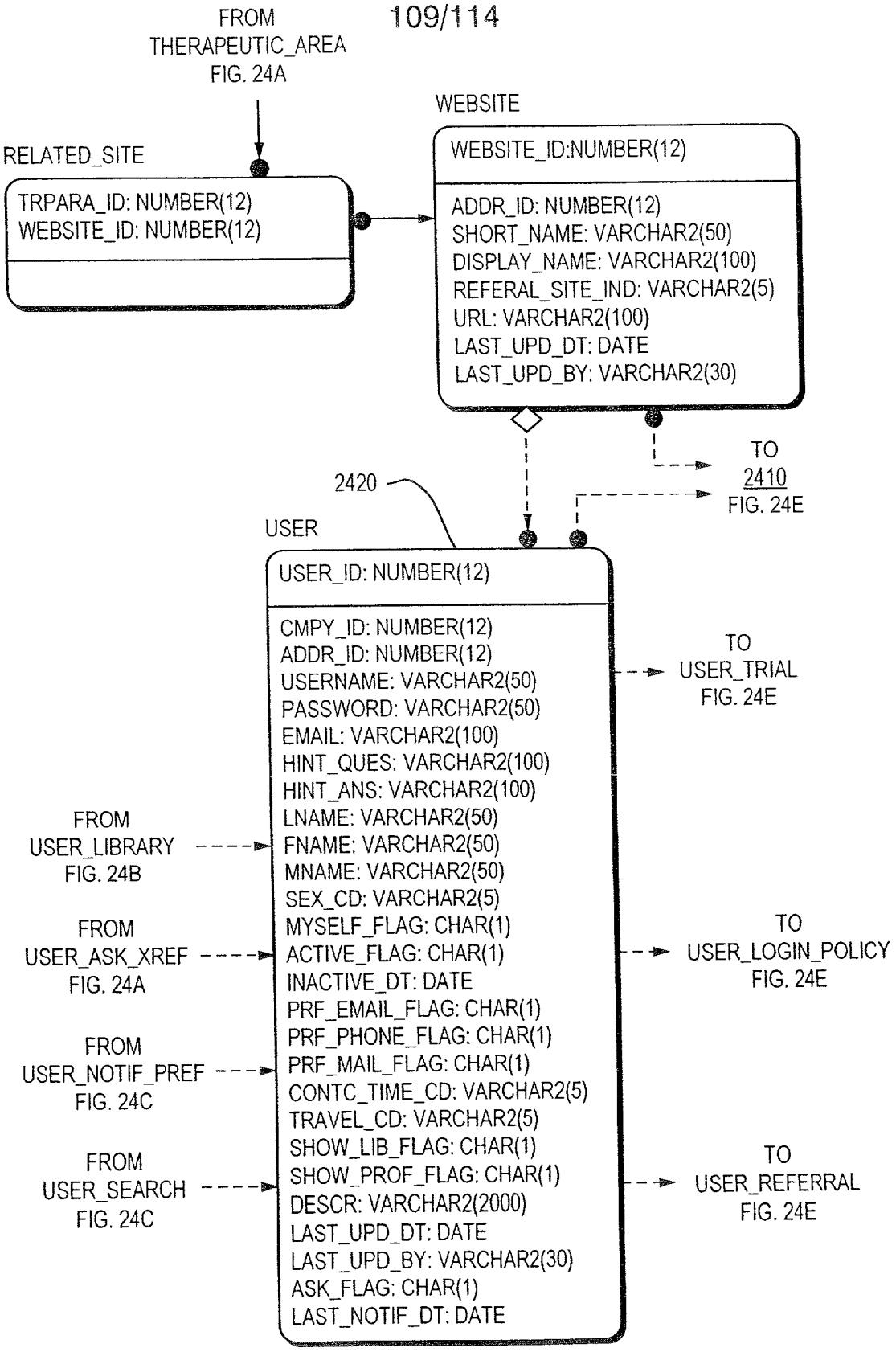

FROM
THERAPEUTIC_AREA
FIG. 24A
WEBSITE
RELATED_SITE
TRPARA_ID: NUMBER(12)
WEBSITE_ID: NUMBER(12)
WEBSITE_ID:NUMBER(12)
ADDR_ID: NUMBER(12)
SHORT_NAME: VARCHAR2(50)
DISPLAY_NAME: VARCHAR2(100)
REFERAL_SITE_IND: VARCHAR2(5)
URL: VARCHAR2(100)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
TO
2410
FIG. 24E
2420
USER
USER_ID: NUMBER(12)
CMPY_ID: NUMBER(12)
ADDR_ID: NUMBER(12)
USERNAME: VARCHAR2(50)
PASSWORD: VARCHAR2(50)
EMAIL: VARCHAR2(100)
HINT_QUES: VARCHAR2(100)
HINT_ANS: VARCHAR2(100)
LNAME: VARCHAR2(50)
FNAME: VARCHAR2(50)
MNAME: VARCHAR2(50)
SEX_CD: VARCHAR2(5)
MYSELF_FLAG: CHAR(1)
ACTIVE_FLAG: CHAR(1)
INACTIVE_DT: DATE
PRF_EMAIL_FLAG: CHAR(1)
PRF_PHONE_FLAG: CHAR(1)
PRF_MAIL_FLAG: CHAR(1)
CONTC_TIME_CD: VARCHAR2(5)
TRAVEL_CD: VARCHAR2(5)
SHOW_LIB_FLAG: CHAR(1)
SHOW_PROF_FLAG: CHAR(1)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ASK_FLAG: CHAR(1)
LAST_NOTIF_DT: DATE
TO
USER_TRIAL
FIG. 24E
FROM
USER_LIBRARY
FIG. 24B
FROM
USER_ASK_XREF
FIG. 24A
FROM
USER_NOTIF_PREF
FIG. 24C
FROM
USER_SEARCH
FIG. 24C
TO
USER_LOGIN_POLICY
FIG. 24E
TO
USER_REFERRAL
FIG. 24E

FIG. 24D

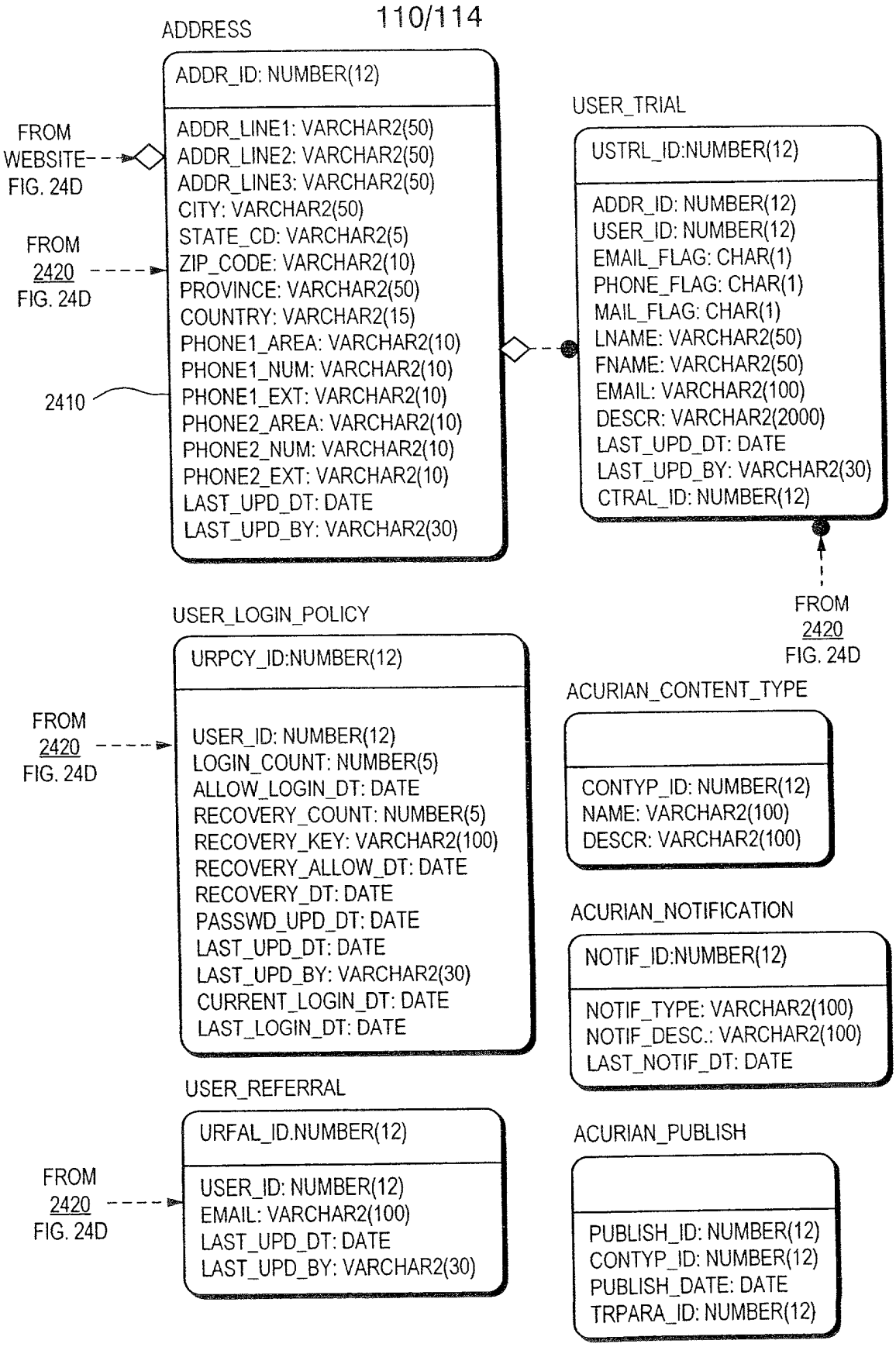

ADDRESS
ADDR_ID: NUMBER(12)
ADDR_LINE1: VARCHAR2(50)
ADDR_LINE2: VARCHAR2(50)
ADDR_LINE3: VARCHAR2(50)
CITY: VARCHAR2(50)
STATE_CD: VARCHAR2(5)
ZIP_CODE: VARCHAR2(10)
PROVINCE: VARCHAR2(50)
COUNTRY: VARCHAR2(15)
PHONE1_AREA: VARCHAR2(10)
PHONE1_NUM: VARCHAR2(10)
PHONE1_EXT: VARCHAR2(10)
PHONE2_AREA: VARCHAR2(10)
PHONE2_NUM: VARCHAR2(10)
PHONE2_EXT: VARCHAR2(10)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
FROM WEBSITE FIG. 24D
FROM 2420 FIG. 24D
2410
USER_TRIAL
USTRL_ID:NUMBER(12)
ADDR_ID: NUMBER(12)
USER_ID: NUMBER(12)
EMAIL_FLAG: CHAR(1)
PHONE_FLAG: CHAR(1)
MAIL_FLAG: CHAR(1)
LNAME: VARCHAR2(50)
FNAME: VARCHAR2(50)
EMAIL: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
CTRAL_ID: NUMBER(12)
FROM 2420 FIG. 24D
USER_LOGIN_POLICY
URPCY_ID:NUMBER(12)
USER_ID: NUMBER(12)
LOGIN_COUNT: NUMBER(5)
ALLOW_LOGIN_DT: DATE
RECOVERY_COUNT: NUMBER(5)
RECOVERY_KEY: VARCHAR2(100)
RECOVERY_ALLOW_DT: DATE
RECOVERY_DT: DATE
PASSWD_UPD_DT: DATE
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
CURRENT_LOGIN_DT: DATE
LAST_LOGIN_DT: DATE
FROM 2420 FIG. 24D
ACURIAN_CONTENT_TYPE
CONTYP_ID: NUMBER(12)
NAME: VARCHAR2(100)
DESCR: VARCHAR2(100)
ACURIAN_NOTIFICATION
NOTIF_ID:NUMBER(12)
NOTIF_TYPE: VARCHAR2(100)
NOTIF_DESC.: VARCHAR2(100)
LAST_NOTIF_DT: DATE
USER_REFERRAL
URFAL_ID.NUMBER(12)
USER_ID: NUMBER(12)
EMAIL: VARCHAR2(100)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
FROM 2420 FIG. 24D
ACURIAN_PUBLISH
PUBLISH_ID: NUMBER(12)
CONTYP_ID: NUMBER(12)
PUBLISH_DATE: DATE
TRPARA_ID: NUMBER(12)

FIG. 24E

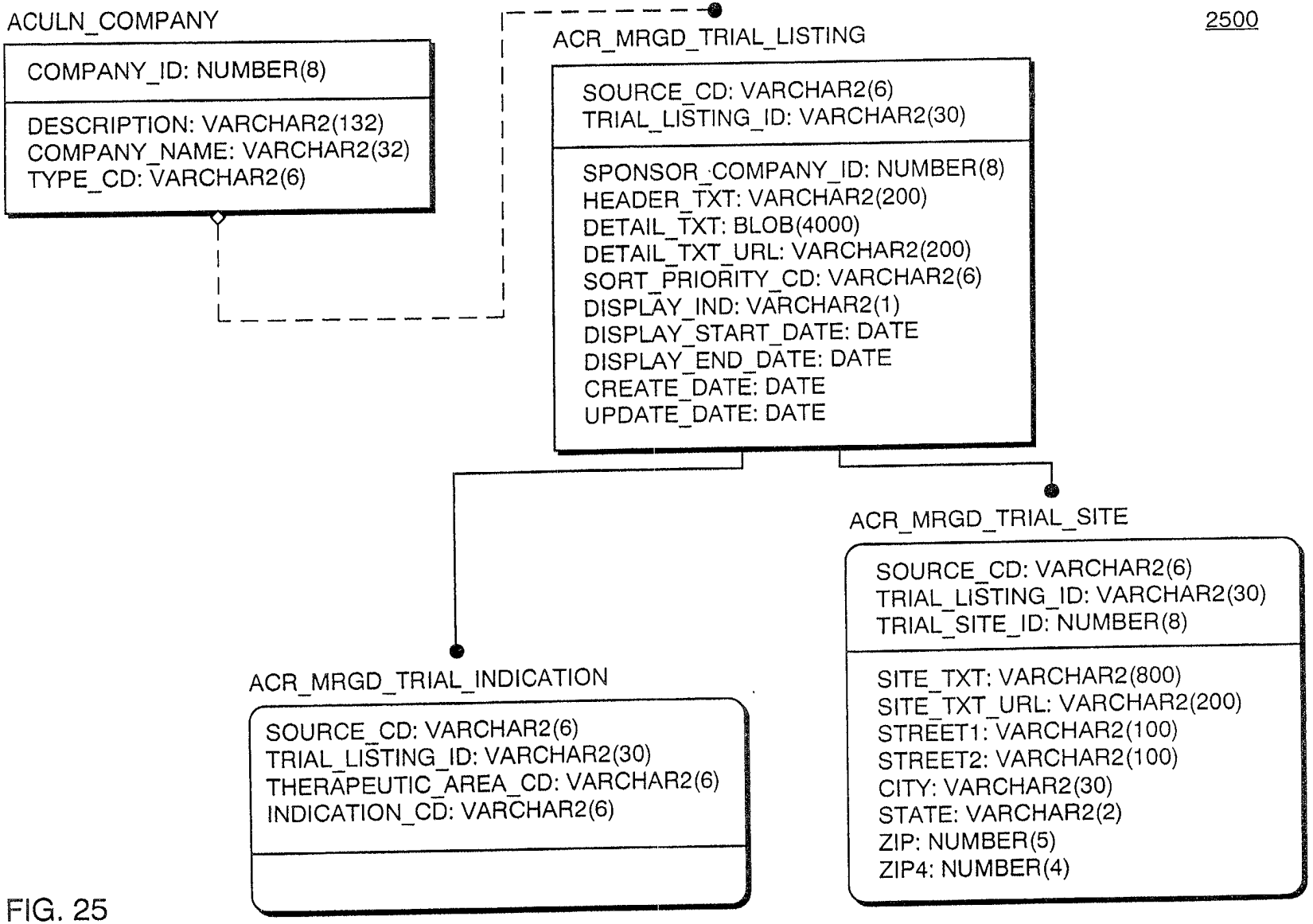

ACULN_COMPANY
COMPANY_ID: NUMBER(8)
DESCRIPTION: VARCHAR2(132)
COMPANY_NAME: VARCHAR2(32)
TYPE_CD: VARCHAR2(6)
ACR_MRGD_TRIAL_LISTING
SOURCE_CD: VARCHAR2(6)
TRIAL_LISTING_ID: VARCHAR2(30)
SPONSOR_COMPANY_ID: NUMBER(8)
HEADER_TXT: VARCHAR2(200)
DETAIL_TXT: BLOB(4000)
DETAIL_TXT_URL: VARCHAR2(200)
SORT_PRIORITY_CD: VARCHAR2(6)
DISPLAY_IND: VARCHAR2(1)
DISPLAY_START_DATE: DATE
DISPLAY_END_DATE: DATE
CREATE_DATE: DATE
UPDATE_DATE: DATE
2500
ACR_MRGD_TRIAL_SITE
SOURCE_CD: VARCHAR2(6)
TRIAL_LISTING_ID: VARCHAR2(30)
TRIAL_SITE_ID: NUMBER(8)
SITE_TXT: VARCHAR2(800)
SITE_TXT_URL: VARCHAR2(200)
STREET1: VARCHAR2(100)
STREET2: VARCHAR2(100)
CITY: VARCHAR2(30)
STATE: VARCHAR2(2)
ZIP: NUMBER(5)
ZIP4: NUMBER(4)
ACR_MRGD_TRIAL_INDICATION
SOURCE_CD: VARCHAR2(6)
TRIAL_LISTING_ID: VARCHAR2(30)
THERAPEUTIC_AREA_CD: VARCHAR2(6)
INDICATION_CD: VARCHAR2(6)

FIG. 25

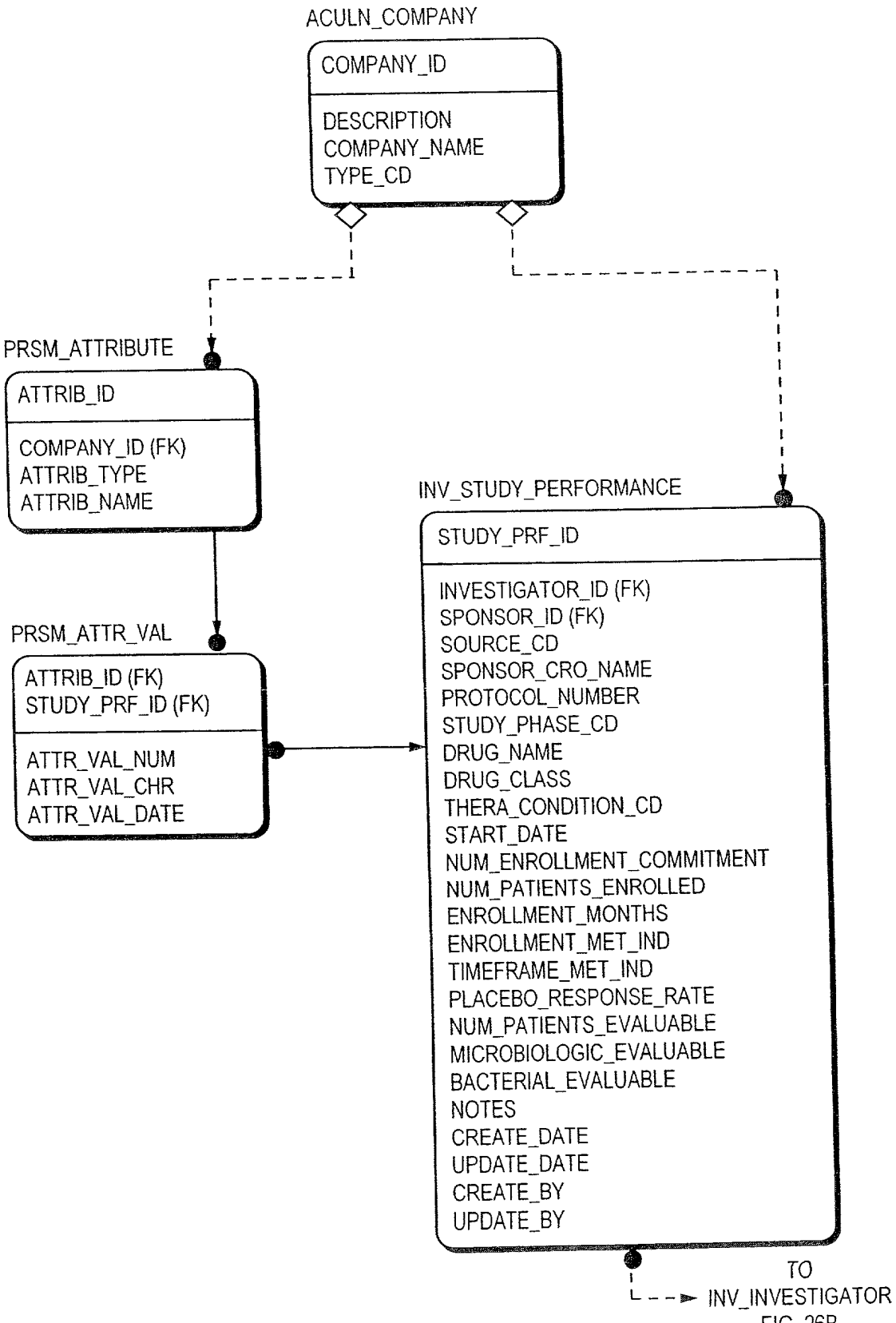

ACULN_COMPANY
COMPANY_ID
DESCRIPTION
COMPANY_NAME
TYPE_CD
PRSM_ATTRIBUTE
ATTRIB_ID
COMPANY_ID (FK)
ATTRIB_TYPE
ATTRIB_NAME
PRSM_ATTR_VAL
ATTRIB_ID (FK)
STUDY_PRF_ID (FK)
ATTR_VAL_NUM
ATTR_VAL_CHR
ATTR_VAL_DATE
INV_STUDY_PERFORMANCE
STUDY_PRF_ID
INVESTIGATOR_ID (FK)
SPONSOR_ID (FK)
SOURCE_CD
SPONSOR_CRO_NAME
PROTOCOL_NUMBER
STUDY_PHASE_CD
DRUG_NAME
DRUG_CLASS
THERA_CONDITION_CD
START_DATE
NUM_ENROLLMENT_COMMITMENT
NUM_PATIENTS_ENROLLED
ENROLLMENT_MONTHS
ENROLLMENT_MET_IND
TIMEFRAME_MET_IND
PLACEBO_RESPONSE_RATE
NUM_PATIENTS_EVALUABLE
MICROBIOLOGIC_EVALUABLE
BACTERIAL_EVALUABLE
NOTES
CREATE_DATE
UPDATE_DATE
CREATE_BY
UPDATE_BY
TO
INV_INVESTIGATOR
FIG. 26B

FIG. 26A

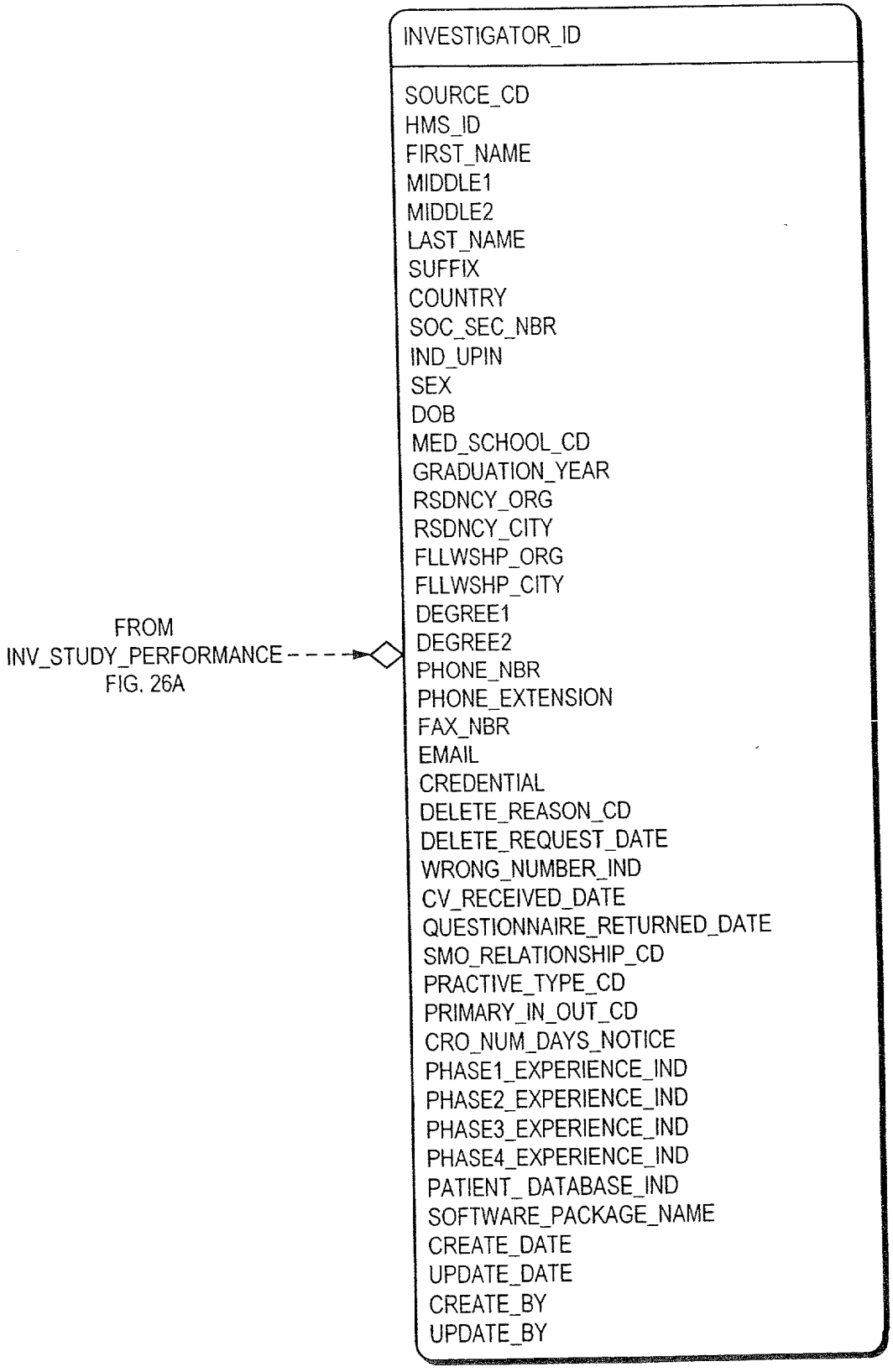

INV_INVESTIGATOR
INVESTIGATOR_ID
SOURCE_CD
HMS_ID
FIRST_NAME
MIDDLE1
MIDDLE2
LAST_NAME
SUFFIX
COUNTRY
SOC_SEC_NBR
IND_UPIN
SEX
DOB
MED_SCHOOL_CD
GRADUATION_YEAR
RSDNCY_ORG
RSDNCY_CITY
FLLWSHP_ORG
FLLWSHP_CITY
DEGREE1
DEGREE2
PHONE_NBR
PHONE_EXTENSION
FAX_NBR
EMAIL
CREDENTIAL
DELETE_REASON_CD
DELETE_REQUEST_DATE
WRONG_NUMBER_IND
CV_RECEIVED_DATE
QUESTIONNAIRE_RETURNED_DATE
SMO_RELATIONSHIP_CD
PRACTIVE_TYPE_CD
PRIMARY_IN_OUT_CD
CRO_NUM_DAYS_NOTICE
PHASE1_EXPERIENCE_IND
PHASE2_EXPERIENCE_IND
PHASE3_EXPERIENCE_IND
PHASE4_EXPERIENCE_IND
PATIENT_ DATABASE_IND
SOFTWARE_PACKAGE_NAME
CREATE_DATE
UPDATE_DATE
CREATE_BY
UPDATE_BY
FROM
INV_STUDY_PERFORMANCE
FIG. 26A

FIG. 26B

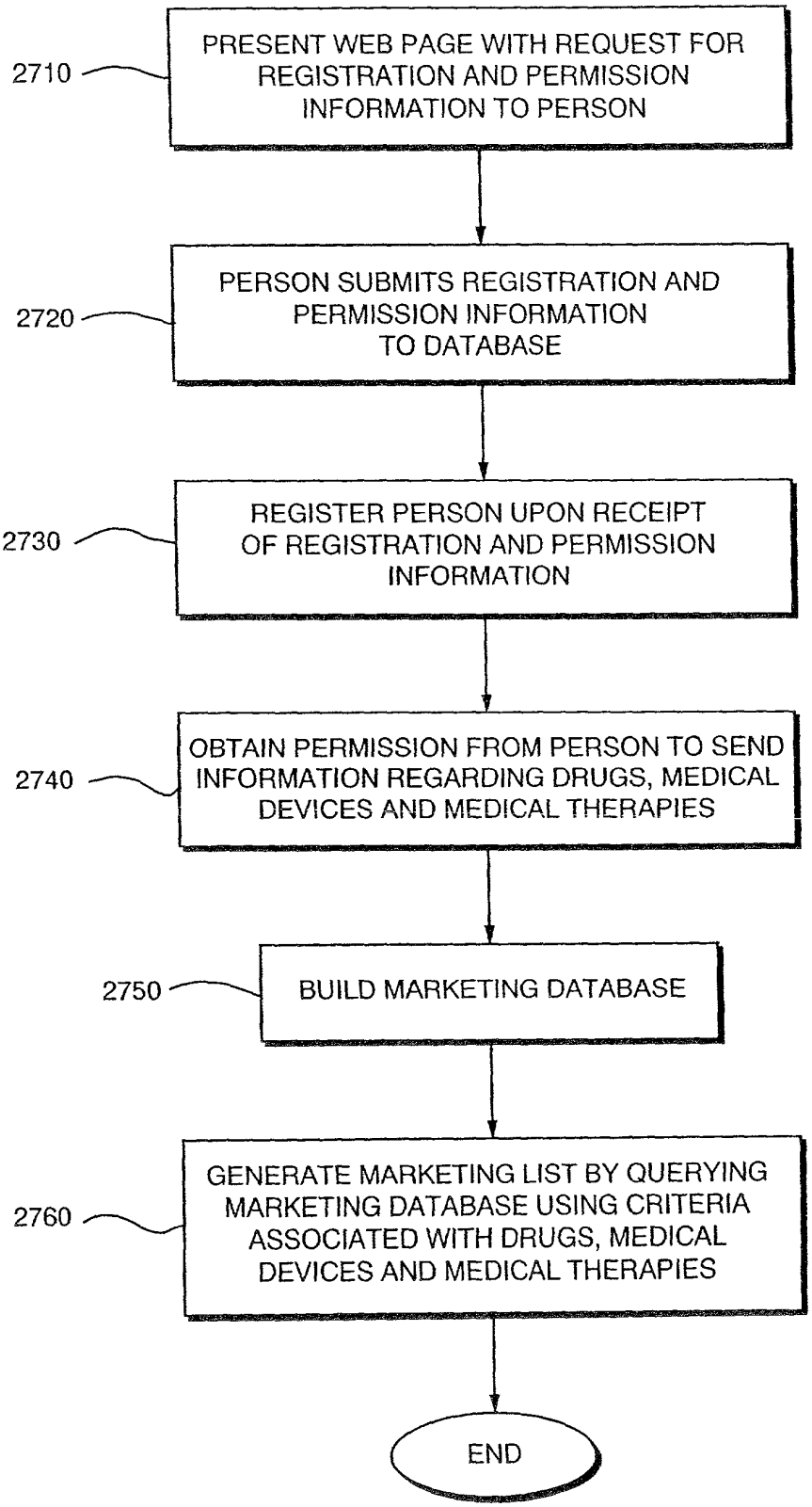

2710
PRESENT WEB PAGE WITH REQUEST FOR REGISTRATION AND PERMISSION INFORMATION TO PERSON
2720
PERSON SUBMITS REGISTRATION AND PERMISSION INFORMATION TO DATABASE
2730
REGISTER PERSON UPON RECEIPT OF REGISTRATION AND PERMISSION INFORMATION
2740
OBTAIN PERMISSION FROM PERSON TO SEND INFORMATION REGARDING DRUGS, MEDICAL DEVICES AND MEDICAL THERAPIES
2750
BUILD MARKETING DATABASE
2760
GENERATE MARKETING LIST BY QUERYING MARKETING DATABASE USING CRITERIA ASSOCIATED WITH DRUGS, MEDICAL DEVICES AND MEDICAL THERAPIES
END

FIG. 27